

**HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
DECEMBER 17, 2014
APPLICATION SUMMARY**

NAME OF PROJECT: Sumner Regional Medical Center

PROJECT NUMBER: CN1409-041

ADDRESS: 225 Big Station Camp Road
Gallatin (Sumner County), TN 37066

LEGAL OWNER: Sumner Regional Medical Center, LLC
330 Seven Springs Way
Brentwood, TN 37027

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Michael Herman
(615) 328-6695

DATE FILED: September 15, 2014

PROJECT COST: \$2,887,396.00 (revised)

FINANCING: Cash Reserves

PURPOSE FOR FILING: Initiation of positron emission tomography (PET) services

DESCRIPTION:

Sumner Regional Medical Center (SRMC), a 155 licensed bed acute care hospital, is seeking approval to purchase a GE Optima PET/CT 560 fixed imaging system and initiate PET services on its existing outpatient campus under the hospital's license. As part of the project, the applicant plans to renovate approximately 1,425 square feet (SF) of space in the existing outpatient building to house a scanning room and support space for the service.

SPECIFIC CRITERIA AND STANDARDS REVIEW:

POSITRON EMISSION TOMOGRAPHY SERVICES

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

The applicant does not project volumes that will reach the minimum PET procedures as projected utilization is 241 in Year 1 increasing to 337 PET procedures in Year 2. The applicant alleges there is a need based on the absence of providers, the development of comprehensive services for its existing cancer program, the high cancer incident rates in the 2-county primary service area and the hardships many residents face by having to travel large distances to PET providers outside the service area. The applicant also notes that the project is financially viable based on positive operating margin performance of approximately 2.7% of gross revenue in Year 2.

The applicant does not meet this criterion.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

The applicant addressed this criterion in Item 6 of the 9/25/14 supplemental response. The proposed site of the PET service is Sumner Station, SRMC's

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outpatient campus, located in Gallatin approximately 6.9 miles from the hospital, 10 miles from Hendersonville and 35 miles from Lafayette in Macon County. The site is accessible to at least 75% of the residents of Sumner and Macon County.

It appears that this criterion has been met.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

There are no other PET providers in the primary service area. The applicant was previously approved for a 1 day per week mobile PET service in CN0406-058AS but did not implement the service and surrendered the CON in December 2007 largely due to the bankruptcy of its former owner.

The applicant believes the project is cost effective because it makes use of an existing building on the hospital's existing 23 acre outpatient campus and complements its existing radiation, medical and surgical cancer program service lines.

It appears that this criterion has been met.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

This criterion is not applicable to the applicant's project.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures per day x 250 days/year = 2,000 procedures per year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600

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stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

There are no existing PET services in the primary service area. The applicant does not expect to meet the utilization standard for a stationary or fixed PET unit operated under the hospital's license on its outpatient campus.

It appears that this criterion does not apply to the project.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.

- a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

A FDA approval letter was included in the attachments to the application.

It appears that this criterion has been met.

- b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

A letter dated 8/15/14 from the architectural firm indicating compliance with current building and safety codes that apply to the proposed fixed PET service is included as an attachment in the application. The applicant also maintains that the proposed PET service will be operated under the same radiation therapy standards set forth in the hospital's radiation safety manual.

It appears that this criterion has been met.

- c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

The applicant will be licensed and operated as part of the hospital and subject to the same emergency management plan and procedures that apply. Patients with a medical emergency will be transported by ambulance from Sumner Station to the main hospital campus in Gallatin, a distance of approximately 6.9 miles.

It appears that this criterion has been met.

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- d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

Draft protocols to assure medical appropriateness and medical necessity were included in the application. The applicant states that physicians who refer patients to the proposed hospital PET service will have no financial interest in SRMC or the PET service. PET procedures will be performed when medically necessary as determined by the independent medical judgment of the referring physician.

It appears that this criterion has been met.

- e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Dr. Glen Nabors, a board certified Radiologist with Sumner Radiology, PC, will be the medical director of the proposed PET/CT service. Arrangements with other physicians PET imaging interpretation services are also in place. Resumes for these individuals are included in the application.

It appears that this criterion has been met.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

As noted, the PET service will be operated by SRMC as a part of the hospital subject to all existing emergency management policies and

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procedures. The Medical Director will remain an active member of the SRMC medical staff.

It appears that this criterion has been met.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant states it will comply with all requests from the HSDA for timely data.

It appears that the applicant intends to meet these criteria.

8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

The applicant states that all of Macon County and part of Sumner County are medically underserved areas as designated by the U.S. Health Resources and Services Administration.

It appears that this criterion has been met.

- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

The applicant requests special consideration for this standard based on the cancer prevalence rates in Macon and Sumner Counties that are 16% and 2.3% higher, respectively, than the statewide cancer rate of 476.8 per 100,000 population as published by TDH in its report, Cancer in Tennessee 2005-2009.

- c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

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The applicant is not a safety net or children's hospital. Criterion is not applicable.

- d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant participates in all area TennCare MCOs and in Medicare.

It appears that this criterion has been met.

Staff Summary

The following information is a summary of the original application and all supplemental responses. Any staff comments or notes, if applicable, will be in bold italics.

Sumner Regional Medical Center (SRMC) operates a 155 licensed bed hospital and an outpatient campus in Sumner County under the same license. The applicant seeks approval to initiate and operate a positron emission tomography (PET) service in an existing building located on SRMC's 24.6 acre outpatient campus at 225 Big Station Camp Boulevard, Gallatin (Sumner County), TN, a distance of approximately 6.9 miles from the main hospital campus. As part of the project, the applicant will renovate approximately 1,425 square feet of space for the PET service to house the scanning room and support space for the fixed unit in the existing 95,998 SF 2-story outpatient facility. The hours and days of operation will be 0800 AM - 4:30 PM, Monday - Friday. If approved, the applicant plans to initiate the proposed PET service in December, 2015.

SRMC received HSDA approval in 2004 for a mobile PET service 1 day per week on the hospital campus (CN0406-058AVS). The service was not implemented and was surrendered to HSDA in December 2007. Per Item 2 of the 9/25/14 supplemental response, the applicant states that the reason was due to financial problems under previous ownership that ultimately lead to bankruptcy and acquisition by Lifepoint Hospitals.

The hospital's total licensed bed complement consists of 155 licensed hospital beds as follows: 90 medical, 15 obstetrical, 18 ICU/CCU, 20 rehabilitation and 12 inpatient geriatric psychiatric beds. Although all of the licensed beds are presently staffed, review of the Joint Annual Report revealed that 133 beds were staffed in calendar year (CY) 2013. Based on 33,900 total inpatient days, SRMC's licensed and staffed hospital bed occupancy was 60% and 70%, respectively,

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during the period. According to the Department of Health and pertaining to the Joint Annual Reports, the following defines the two bed categories:

Licensed Beds- The maximum number of beds authorized by the appropriate state licensing (certifying) agency or regulated by a federal agency. This figure is broken down into adult and pediatric beds and licensed bassinets (neonatal intensive or intermediate care bassinets).

Staffed Beds-The total number of adult and pediatric beds set up, staffed and in use at the end of the reporting period. This number should be less than or equal to the number of licensed beds.

Ownership

- Sumner Regional Medical Center (STMC) is owned by LifePoint Hospitals, Inc.
- Lifepoint operates a total of 63 hospitals in 20 states, including 10 hospitals in Tennessee.
- Attachment A.4 contains an organizational chart and a list of facilities owned by LifePoint Hospitals, Inc.

Facility Information

- If approved, will be only provider of PET service in Sumner and Macon Counties.
- Proposed site of PET service is existing 95,998 square foot 2-story building on a 26 acre outpatient campus. Building was constructed in 2007.
- Current occupants on SRMC's outpatient campus (imaging, rehabilitation and sports medicine) utilize approximately 21,660 square feet or 23% of the total building space.
- SRMC is modernizing its oncology program. This project and recently approved linear accelerator service project, CN1408-036A, provide core diagnosis and treatment service support.
- Hospital will provide transportation of inpatients to the Sumner Station outpatient campus by ambulance.
- A floor plan drawing of the proposed site is included as Attachment B.IV.

PET/CT Equipment

- Proposed GE Optima PET/CT scanner will provide physicians and members of SRMC's oncology team the latest state of the art imaging technology for diagnoses of cancer. A 16-Slice computed tomography component will also provide low dose, multiple imaging clinical applications.
- The vendor quote for purchase of the PET unit with taxes, shipping and 5-

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year service agreement is \$1,698,228.00. The expiration date of the vendor quote was extended in the 9/25/14 supplemental response to 12/22/14.

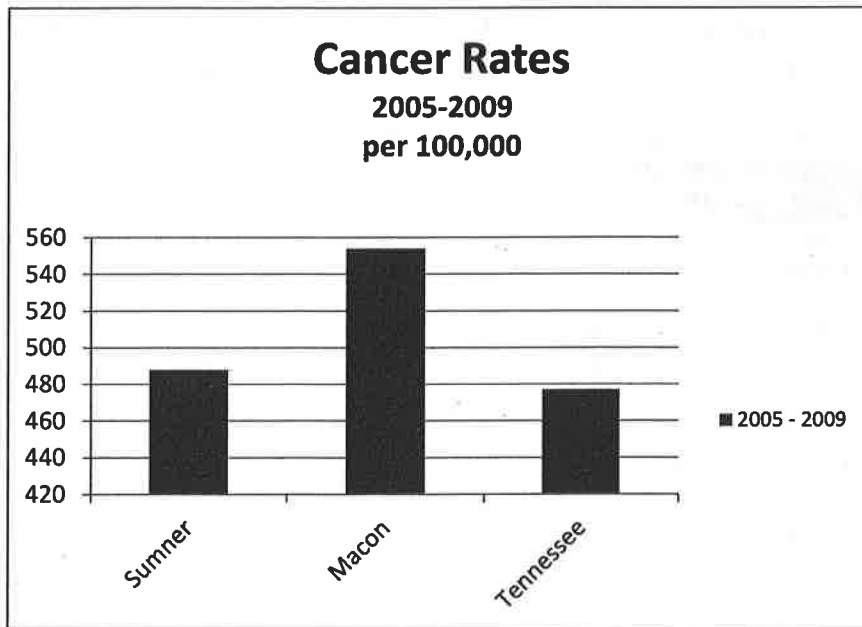
- New technology upgrades include integrated PET and CT scanning, processing, review and data management functionality.
- The radiopharmaceutical material (FDG) will be provided by Cardinal Health, in accordance with owner's longstanding vendor relationship. The vendor's cyclotron is located in Louisville, Kentucky, a distance of approximately 160 miles from Sumner Station.

Project Need

The applicant identified the need for the project based on the fixed PET unit's intended use for its cancer program and the lack of a PET service in its 2-county service area. The following items summarize the need for the project:

- Enhance access of residents in service area to new PET service focusing on the diagnosis of cancer and reduce outmigration to more distant providers.
- Continue commitment to modernization and enhancement of cancer diagnosis and treatment service capabilities.
- Develop array of cancer services focusing on diagnostic, treatment, and support services such as community education, pastoral care, patient support groups and nutrition services.
- Respond to needs of older population.
- Target high incidence of cancer in Macon and Sumner Counties as illustrated in the graph below.

Service Area Cancer Rates Age Adjusted Rates per 100,000 Population



Source: Tennessee Cancer Registry Annual Reports; CN1408- 036, Item 7, 8/26/14 supplemental response

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- As indicated by the table, both counties had cancer rates per 100,000 population for the years 2005-2009 higher than the statewide rate of 477 per 100,000 population.
- Tennessee had a cancer incidence rate ranked 16th highest in the country. Its cancer mortality rate was ranked 6th highest.

Primary Service Area

The service area of SRMC's existing radiation therapy service is Sumner and Macon Counties.

- Per the TDH summary report, the total population of the primary service area is estimated at 195,450 residents in calendar year CY 2014 increasing by approximately 6.2% to 207,527 residents in CY 2018.
- The total population of the state of Tennessee is expected to grow 2.8% from CY2014 to CY2018.
- The total 65+ age population is estimated at 28,811 residents in CY 2014 increasing approximately 12.9% to 32,539 residents in 2018 compared to a statewide change of 9.18% during this time period.
- The age 65 and older population accounts for approximately 15.9% of the total service area population compared to 15.8% statewide.
- The applicant estimates that approximately 15.4% of Sumner and Macon County residents are enrolled in TennCare compared to 18.8% statewide.

Historical and Projected Utilization

SRMC is seeking approval to initiate a new PET service on its outpatient campus in a 2-county primary service area (PSA) that has no PET providers. The majority of residents travel to providers outside the PSA, primarily to providers in Davidson County. The use of other PET providers outside the applicant's PSA by residents of Sumner and Macon Counties is shown in the table below.

PET Provider Utilization by PSA Residents

	2011	2012	2013	% Change '11-'13
Procedures at Davidson Co PET providers	700	687	684	-2.3%
At Other TN Providers	31	21	20	-35.5%
Total PSA Resident Procedures	731	708	704	-3.7%
Total Procedures of Davidson Co. Providers	7,594	7,302	7,262	-4.4%
Dependence on PSA Residents by Davidson Co. Providers	9.2%	9.4%	9.4%	NA

Source: HSDA Equipment Registry as of 11/4/14

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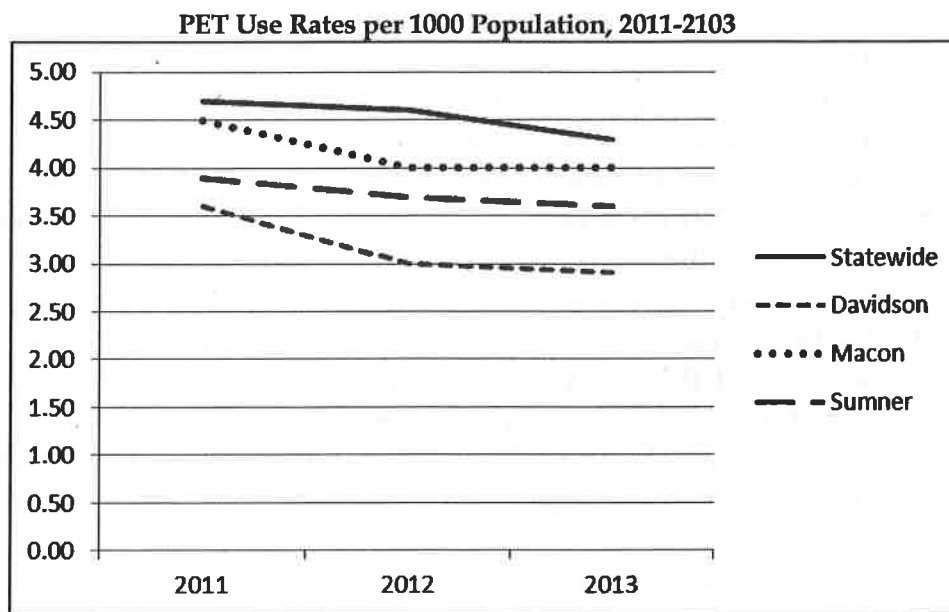
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The use rate by service area residents (PET procedures per 1,000 population) compared to Davidson County and TN resident use rates is illustrated in the tables below.

PET Use Rates of Residents in SRMC Service Area, Davidson County, and Tennessee

County	2011 procedures	2011 Use Rate	2012 procedures	2012 Use rate	2013 Procedures	2013 Use Rate
Macon	101	4.5	90	4.0	92	4.0
Sumner	630	3.9	618	3.7	611	3.6
Davidson	2,384	3.6	1,896	3.0	1,893	2.9
Statewide	29,704	4.7	29,724	4.6	28,086	4.3



Based on the tables above, the following highlights are noted:

- On average, approximately 96% of total PET procedures by Macon and Sumner County residents were performed at Davidson County PET provider sites from 2011 – 2013.
- Residents of the applicant's service area accounted for approximately 9% of Davidson County PET provider total volumes from 2011 to 2013.
- The chart and trend line graph reflects that the 3 Middle TN county PET use rates and the statewide use rate appear to be trending downward during the period.
- Of the 3 Middle Tennessee counties, the PET use rate in Davidson County was the lowest from 2011 – 2013.

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The applicant projects 241 PET procedures in Year 1 increasing by 39.8% to 337 procedures in Year 2. Per Item 8m of the 9/25/14 supplemental response, SRMC developed its projections for the PET service in light of the historical levels of outmigration by residents of the service area and input from a member of a large oncology practice who is familiar with SRMC's cancer program and service (letter from this individual is in 9/25/14 supplemental response). Additionally, the applicant states that projected utilization may be higher in consideration of recent changes by the Centers for Medicare and Medicaid Services (CMS) effectively expanding covered PET services. A description of these coverage changes was provided in a bulletin from GE Healthcare in the 9/25/14 supplemental response.

Project Cost

Major costs are:

- Purchase of PET/CT unit at a total revised cost of \$1,698,228, inclusive of 5-year maintenance, sales tax, and freight (58.8% of the total project cost).
- Build-out cost of \$460,000 for 1,425 square foot PET service area suite in SRMC's existing outpatient facility (15.9% of the total project cost).
- Architect letter dated 8/15/14 attests to construction cost estimate and build-out in accordance with all applicable building and safety codes.
- Per HSDA records, the project's combined construction cost of \$322.80 per square foot (SF) is above the HSDA 3rd quartile combined construction cost of \$274.63/SF for hospital projects from 2011 -2013.
- For other details on Project Cost, see the revised Project Cost Chart on page 20-R of the original application.

Historical Data Chart

The PET service is a new service line for the hospital and has no prior record of fiscal operations. Highlights of SRMC's overall financial performance are as follows: Highlights are as follows:

- According to the revised Historical Data Chart, SRMC reported the following favorable net operating income after capital expenditures; \$4,941,000 in 2011, \$4,304,000 in 2012, and \$6,406,000 for 2013 (average annual operating margin of 1.3% of annual gross operating revenues).
- In the course of HSDA staff review of the application, there appeared to be a difference of approximately \$4.4 million in Net Operating Income as reported in the Historical Data Chart and the Income Statement. Please see the clarification provided in Item 10 of the 9/25/14 supplemental response.

Projected Data Chart

The Projected Data Chart for the applicant's new PET service reflects \$1,808,000 in total gross operating revenue on 241 procedures in Year 1 increasing by approximately 39.8% to \$2,528,000 on 337 procedures in Year Two. The Projected Data Chart reflects the following:

- Net operating income amounts to \$18,000 in Year 1 increasing to \$65,000 in Year 2.
- The operating margin of the PET service amounts to approximately 2.6% of gross revenue in Year 2. The operating margin is lower, in part, as a result of annual maintenance service costs.
- Net operating revenue after bad debt, charity care, and contractual adjustments is expected average approximately 25% of gross revenue in the first two years of the project.
- Contractual adjustments account for the highest deductions from revenue averaging approximately 69% of gross revenue per year. It appears that the applicant's 51.9% Medicare/TennCare payor mix may help explain why contractual adjustments are higher for this service.

Charges

As clarified in Item 11 of the 9/25/14 supplemental response, the average gross charge of \$7,500 per procedure is based on pricing for PET services in Lifepoint hospitals in other states with fixed units. A summary of the applicant's charges for Year 1 of the project is as follows:

- The proposed average gross charge and net charge is \$7,500 and \$1,904.60 per procedure, respectively.
- The applicant states that professional fees for imaging interpretation services will be billed separately by the radiologists.
- Per the comparison provided on page 26 of the application, the Medicare allowable charge for the most common PET procedure classifications that apply to the service range is presently \$1,056.12 per procedure.
- According to the HSDA Equipment Registry, the applicant's \$7,500 gross charge is higher than the 2013 PET median charge of \$4,834.25 and the 3rd Quartile PET Charge of \$7,307.21.
- As noted in Item 11 of the 9/25/14 supplemental response, the applicant states that the proposed charge falls within the range of other Middle TN average PET charges. HSDA records reflect that the charges of the 5 Davidson County PET providers ranged from a low of \$3,349 (Tennessee Oncology) to a high of \$14,928 per procedure in 2013 (TriStar Centennial).

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Payor Mix

- The expected payor mix in Year 1 includes 45.1% for Medicare and 6.6% for TennCare.
- SRMC contracts with all TennCare MCOs in the service area: AmeriGroup, United Healthcare (AmeriChoice), and TennCare Select.
- Per Item 3, Supplemental 2, the applicant states that the Medicare payor mix may increase when adding Medicare Advantage.
- The applicant's commercial and self-pay payor mix is approximately 44.8% and 5.5%, respectively, in Year 1.

Financing

- A letter dated September 9, 2014 from the CFO of the parent company confirms that Lifepoint Hospitals has the cash reserves to fund the estimated capital outlay required for start-up of the applicant's new PET service.
- Review of SRMC's Balance Sheet for the period ending December 13, 2013 revealed \$22,490,955 in total current assets, total current liabilities of \$7,983,125 and a current ratio of 2.82 to 1.0.
- *Note to Agency Members: current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.*

Staffing

- The service is under the clinical leadership of the hospital's cancer committee and the physician specialists on staff at SRMC involved in cancer care.
- A description of the committee's key activities and the composition of the medical staff associated with SRMC's cancer program was addressed in detail in on page 5 of the application and page 3 of the 9/25/14 supplemental response.
- The proposed staffing pattern of the service consists of 1.0 full time equivalent (FTE) nuclear medicine technologist. Other support staff, such as clerical and nursing staff, may be used from SRMC's existing radiation therapy cancer program as necessary.

Licensure/Accreditation

- SRMC is accredited by The Joint Commission and licensed by TDH. The applicant's cancer program is accredited by the American College of Surgeons Commission on Cancer Care.

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The applicant has submitted the required information on corporate documentation, site control and a revised quote for the purchase of the PET/CT unit inclusive of costs for maintenance/service and accessories that will be effective on the date of the Agency hearing of the application. Staff will have a copy of these documents available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency's office.

Should the Agency vote to approve this project, the CON would expire in three years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent, denied or pending applications for this applicant.

Outstanding Certificates of Need

Sumner Regional Medical Center, CN1408-036A, has an outstanding Certificate of the Need that will expire on December 1, 2017. The project was approved under CONSENT CALENDAR REVIEW at the October 22, 2014 Agency meeting for the relocation of the hospital's existing linear accelerator service from its main campus to its outpatient campus at Sumner Station, Gallatin, (Sumner County), TN. The project includes the replacement and upgrade of the current unit and the build-out of space in the existing outpatient building. The estimated project cost is **\$10,512,421**. *Project Status Update: the project was recently approved.*

LifePoint Hospitals, Inc. has a financial interest in this application and the following:

Outstanding Certificates of Need

Starr Regional Medical Center—Etowah, CN1404-009A, has an outstanding Certificate of Need that will expire on September 1, 2017. The project was approved at the July 23, 2014 Agency meeting for the expansion of the hospital's existing ten (10) bed geri-psychiatric unit to fourteen (14) beds. The hospital will close four (4) general hospital beds at Etowah with the result that the licensed beds at Etowah (72) and the total consolidated licensed beds (190) for both the Etowah and Athens hospitals will not change. The estimated project cost is **\$1,283,000**. *Project Status Update: the project was recently approved.*

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CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent, pending or denied applications, or outstanding Certificates of Need for other health care organizations proposing this type of service.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG
(11/6/14)

LETTER OF INTENT



State of Tennessee
Health Services and Development Agency
 Andrew Jackson Building, 9th Floor
 502 Deaderick Street
 Nashville, TN 37243
www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in The Tennessean which is a newspaper
 of general circulation in Sumner Tennessee, on or before September 10, 20 14,
 for one day.
 (Name of Newspaper) (County) (Month / day) (Year)

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Sumner Regional Medical Center a hospital
 (Name of Applicant) (Facility Type-Existing)
 owned by: Sumner Regional Medical Center, LLC with an ownership type of limited liability Company

intends to file an application for a Certificate of Need to initiate positron emission tomography ("PET") service at its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard, Gallatin, Tennessee. The project will require build-out of approximately 1,425 square feet of existing space and the purchase of G.E. Discovery PET/CT Imaging System. The total project cost is approximately \$2,687,896. The project does not involve a change in licensed bed capacity or the initiation of any service requiring a certificate of need, except positron emission tomography.

The anticipated date of filing the application is: September 15, 20 14

The contact person for this project is Dan Elrod Attorney
 (Contact Name) (Title)

who may be reached at: Butler Snow LLP 150 3rd Avenue South, Suite 1600
 (Company Name) (Address)

Nashville TN 37201 615 / 651-6702
 (City) (State) (Zip Code) (Area Code / Phone Number)

[Signature] 9/10/2014 dan.elrod@butlersnow.com
 (Signature) (Date) (E-mail Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

ORIGINAL APPLICATION

SEP 15 14 02:05

Sumner Regional Medical Center

Certificate of Need Application

To Initiate Positron Emission Tomography ("PET") Services at Sumner Station

September 15, 2014

September 25, 2014
4:05pm

1. **Name of Facility, Agency, or Institution**

Sumner Regional Medical Center (for its Sumner Station Campus)

Name

225 Big Station Camp Road

Street or Route

Sumner

County

Gallatin

City

TN

State

37066

Zip Code

2. **Contact Person Available for Responses to Questions**

Michael Herman

Name

Chief Operating Officer

Title

Sumner Regional Medical Center

Company Name

Michael.Herman@LPNT.net

Email address

555 Hartsville Pike

Street or Route

Gallatin

City

TN

State

37066

Zip Code

COO

Association with Owner

615-328-6695

Phone Number

Fax Number

3. **Owner of the Facility, Agency or Institution**

Sumner Regional Medical Center, LLC

Name

615-920-7000

Phone Number

330 Seven Springs Way

Street or Route

Sumner

County

Brentwood

City

TN

State

37027

Zip Code

See Attachment A, Item 3

4. **Type of Ownership of Control (Check One)**

A. Sole Proprietorship

B. Partnership

C. Limited Partnership

D. Corporation (For Profit)

E. Corporation (Not-for-Profit)

F. Government (State of TN or
Political Subdivision)

G. Joint Venture

H. Limited Liability Company

I. Other (Specify)

X

See Attachment A, Item 4

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5. **Name of Management/Operating Entity (If Applicable)**

N/A

Name _____

Street or Route _____

County _____

City _____

State _____

Zip Code _____

**PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

6. **Legal Interest in the Site of the Institution (Check One)**

A. Ownership

X

D. Option to Lease

B. Option to Purchase

E. Other (Specify) _____

C. Lease of _____ Years

**PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

See Attachment A, Item 6

7. **Type of Institution (Check as appropriate--more than one response may apply)**A. Hospital (Specify) acute careX

H. Nursing Home

B. Ambulatory Surgical Treatment
Center (ASTC), Multi-Specialty

I. Outpatient Diagnostic Center

C. ASTC, Single Specialty

J. Rehabilitation Facility

D. Home Health Agency

K. Residential Hospice

E. Hospice

L. Nonresidential

F. Mental Health Hospital

Substitution-Based Treatment
Center for Opiate AddictionG. Intellectual Disability
Institutional Habilitation Facility

M. Birthing Center

(IDIHF) (ICF/IID formerly
(ICF/MR)

N. Other Outpatient Facility

O. Other (Specify) _____

8. **Purpose of Review (Check as appropriate--more than one response may apply)**

A. New Institution

G. Change in Bed Complement

B. Replacement/Existing Facility

*[Please note the type of change
by underlining the appropriate
response: Increase, Decrease,
Designation, Distribution,
Conversion, Relocation]*

C. Modification/Existing Facility

D. Initiation of Health Care

Service as defined in TCA §
68-11-1607(4)

H. Change of Location

(Specify) Positron Emission TomographyX

I. Other (Specify) _____

E. Discontinuance of OB Services

F. Acquisition of Equipment

9. **Bed Complement Data****Please indicate current and proposed distribution and certification of facility beds.**

	<u>Current Beds</u>		<u>Staffed</u>	<u>Beds</u>	<u>TOTAL</u>
	<u>Licensed</u>	<u>*CON</u>	<u>Beds</u>	<u>Proposed</u>	<u>Beds at Completion</u>
A. Medical	90	0	90	0	90
B. Surgical					
C. Long-Term Care Hospital					
D. Obstetrical	15	0	15	0	15
E. ICU/CCU	18	0	18	0	18
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric	12		12		12
J. Child/Adolescent Psychiatric					
K. Rehabilitation	20		20		20
L. Nursing Facility - SNF (Medicare only)					
M. Nursing Facility - NF (Medicaid only)					
N. Nursing Facility - SNF/NF (dually certified Medicaid/Medicare)					
O. Nursing Facility - Licensed (non-Certified)					
P. IDIHF					
Q. Adult Chemical Dependency					
R. Child and Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL	155	0	155	0	155

*CON-Beds approved but not yet in service

10. **Medicare Provider Number** 1447571658
Certification Type Acute Care Hospital

11. **Medicaid Provider Number** 044-0003
Certification Type Acute Care Hospital

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?**
 Yes
 No
 X NA

13. **Will this project involve the treatment of TennCare participants?** Yes

NOTE: **Section B** is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. **Section C** addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

- I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility, staffing, and how the project will contribute to the orderly development of adequate and effective healthcare.

Response:

Sumner Regional Medical Center ("SRMC") proposes to initiate Positron Emission Tomography ("PET") service at its existing outpatient campus, known as "Sumner Station," located on Big Station Camp Boulevard just off Vietnam Veterans Parkway, approximately 6.9 miles west of the main campus. PET services are currently not available in the community, and the availability of the service at Sumner Station will alleviate the travel burden on cancer patients who now must drive to Nashville for PET scans.

SRMC is a 155-bed acute care hospital in Gallatin, TN. It is part of LifePoint Hospitals. LifePoint Hospitals is headquartered in Brentwood, TN. It operates 63 hospitals in 20 states, including 10 in Tennessee. SRMC is one of 15 LifePoint hospitals that was recognized by the Joint Commission in 2013 as a Top Performer in Key Quality Measures.

The Sumner Station campus of SRMC was constructed in 2007, and it is a two story building with approximately 95,998 sq. ft. of space. Approximately 11,757 sq. ft. are currently used for outpatient imaging (CT, MRI, ultrasound, mammography and x-ray), and approximately 9,900 sq. ft. are used for outpatient rehabilitation (physical therapy, occupational therapy and speech therapy) and a sports medicine physician. The remaining space will be developed to support the health care needs of the community, including the proposed relocation of radiation therapy and the installation of a PET/CT unit that is the subject of this application.

SRMC's primary service area for radiation therapy is Sumner and Macon Counties, and SRMC believes that its primary service area for PET service will be the same.

The need for the project is based on the lack of PET services in the area. Most patients in the region who need PET scans currently obtain the service in Nashville, approximately 30 miles from Gallatin. The availability of PET services at Sumner Station will alleviate the travel burden on cancer patients. The need for PET services in community is further

supported by the fact that the cancer incidence rates in Sumner and Macon counties are higher than the statewide average. Based on information in the report titled Cancer in Tennessee 2005-2009 published in 2013 by the Division of Policy, Planning and Assessment, Tennessee Department of Health, the following information is relevant:

- For the period 2005-2009, Tennessee had the 16th highest cancer incidence rate in the country and the 6th highest cancer mortality rate.
- Tennessee's cancer incidence rate for the period was 476.8 per 100,000.
- Sumner County's cancer incidence rate for the period was 487.6 per 100,000, 2.3% higher than the Tennessee rate
- Macon County's cancer incidence rate for the period was 554 per 100,000, 16% higher than the Tennessee rate.

Given that cancer occurs with more frequently in the service area than the statewide average, it is important that state of the art cancer diagnostic resources be conveniently available. SRMC is committed to continue the modernization and enhancement of its cancer diagnosis and treatment capabilities, as evidenced by this application for PET services. Mammography and CT imaging services are already provided at Sumner Station.

SRMC's cancer service has been accredited by the American College of Surgeons. In addition to radiation therapy and diagnostic services, SRMC provides an array of cancer support services including community education, pastoral care and nutrition services. Patient support groups are available through a partnership with Gilda's Club. Chemotherapy is provided in the community by Tennessee Oncology, the largest oncology group in the region, which participates in clinical trials through the Sarah C Cannon Center for Cancer Research.

The number and types of physicians on staff at SRMC involved in cancer care are as follows:

- Radiation oncologist – 1 active staff; 10 coverage staff
- Medical oncologist – 2 active staff; 16 consulting/coverage staff
- General Surgeons – 4 active staff
- Urologists – 4 active staff
- Radiologists – 9 active staff
- Pathologists – 4 active staff

The PET service proposed by SRMC will be used for cancer diagnosis and treatment planning only. There are no current plans to provide PET scans for neurological or cardiac patients. The availability of PET at Sumner Station will complement other cancer services in the community, including radiation therapy, chemotherapy and surgery services.

The project will require renovation and build-out of approximately 1,425 sq. ft. of shelled space in an existing building for the scan room and support areas. The PET service will be provided by a G.E. Discovery PET/CT Imaging System, which utilizes integrated PET and CT functionality, a feature that has become the standard for PET services. The total project cost, including the PET/CT unit and maintenance for 5 years is approximately \$2,687,896, which will be funded by a capital contribution from the applicant's parent, LifePoint Hospitals. The only staff required for the project is one (1) nuclear medicine technologist FTE.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. For the establishment or modification of a healthcare institution describe the development of and need for the proposal. Health care institutions include:

1. Nursing home
2. Hospital
3. Ambulatory Surgical Treatment Center
4. Birthing Center
5. Mental Health Hospital
6. Intellectual Disability Institutional Habilitation Facility
7. Home Care Organization (Home Health Agency or Hospice Agency)
8. Outpatient Diagnostic Center
9. Rehabilitation Facility
10. Residential Hospice
11. Nonresidential Substitution-based Treatment Center for Opiate Addiction

Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applications with construction, modification and/or renovation costs should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

Response: The project will require approximately 1,425 sq. ft. of interior renovation for the scan room and support areas.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

Response: Not applicable.

C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

1. Adult Psychiatric Services
2. Hospital-Based Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Burn Units
4. Cardiac Catheterization Services
5. Child and Adolescent Psychiatric Services
6. Extracorporeal Lithotripsy
7. Home Health Services
8. Hospice Services
9. Magnetic Resonance Imaging (MRI)
10. Neonatal Intensive Care Unit
11. Opiate Addiction Treatment provided through a Non-Residential Substitution-Based Treatment Center for Opiate Addiction
12. Open Heart Surgery
13. Positron Emission Tomography
14. Radiation Therapy/Linear Accelerator
15. Rehabilitation Services
16. Swing Beds
17. Discontinuation of any obstetrical or maternity service
18. Closure of a Critical Access Hospital
19. Elimination in a critical access hospital of any service for which a certificate of need is required

Response: *The need for this project is based on current unavailability of PET services in the region. Cancer patients located in the service area must now travel 30 miles or more to Nashville for PET scans that are essential to cancer diagnosis and treatment planning. Many cancer patients are elderly or otherwise frail, and the project will alleviate the travel burden these and other cancer patients now face.*

D. Describe the need to change location or replace an existing facility.

Response: *Not applicable.*

E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$2.0 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. For major medical equipment (not replacing existing equipment):
 - a. Describe the new equipment, including:
 1. Brief description of equipment including characteristics such as fixed or mobile; expected vendor and model (if known); for MRI use descriptors such as Tesla strength, open/closed bore; for linear accelerators use descriptors such as MeV strength, IMRT/IGRT/SRS capability; etc.;
 2. Total cost (As defined by Agency Rule 0720-9-.01(13))
 - a. By Purchase or

b. By Lease;

3. Expected useful life;
4. List of clinical applications to be provided;
5. Documentation of FDA approval; and
6. For mobile major medical equipment list all sites that the unit is currently serving and its current schedule of operations at those sites.

Response: The proposed PET/CT unit is a GE Discovery PET/CT Imaging System. The unit will be purchased, and the total cost of the unit including maintenance for 5 years is \$1,498,728. The unit will be used for cancer diagnosis and treatment planning and evaluation. A copy of the FDA approval is at Attachment B. II, E., 1.

b. Provide current and proposed schedules of operations.

Response: The hours and days of operation of the proposed PET service will be 8:00-4:30.

2. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment.

Response: The PET/CT unit will be purchased. The vendor quote is attached under Attachment B.II, E., 2.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which **must** include:

1. Size of site (*in acres*);
2. Location of structure on the site; and
3. Location of the proposed construction.
4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

Response: Plot plan attached under Attachment B.III.(A).

- (B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients. (***Not applicable to home health or hospice agency applications.***)

Response: Sumner Station is located on Big Station Camp Boulevard, in between Long Hollow Pike and Vietnam Veterans Bypass. There is not direct bus service to the facility, but Sumner Station is easily accessible by car. Additionally, Mid-Cumberland Human Resources Agency RTS Public Transit serves the area.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an

8 1/2" x 11" sheet of white paper. *(Not applicable to home health or hospice agency applications.)*

NOTE: **DO NOT SUBMIT BLUEPRINTS**. Simple line drawings should be submitted and need not be drawn to scale.

Response: The floor plan is attached as Attachment B, IV.

V. For a Home Health Agency or Hospice, identify:

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. *Please type each question and its response on an 8 1/2" x 11" white paper.* All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth, if applicable.
 - a. Please discuss how the proposed project will relate to the 5 Principles for Achieving Better Health found in the State Health Plan. Please list each principle and follow it with a response.

Response:

1. The purpose of the State Health Plan is to improve the health of Tennesseans.
 - a. How will this proposal protect, promote, and improve the health of Tennesseans over time?

- b. What health outcomes will be impacted and how will the applicant measure improvement in health outcomes?
- c. How does the applicant intend to act upon available data to measure its contribution to improving health outcomes?

Response: PET service is an important tool for the diagnosis and treatment of cancer. It is not currently available in the community. This project will facilitate the diagnosis and treatment of cancer making state-of-the-art imaging available at a convenient location that will be more accessible than the existing service. The project will also reduce the stress on sick patients by making it easier to access care.

2. Every citizen should have reasonable access to health care.

- a. How will this proposal improve access to health care? You may want to consider geographic, insurance, use of technology, and disparity issues (including income disparity), among others.
- b. How will this proposal improve information provided to patients and referring physicians?
- c. How does the applicant work to improve health literacy among its patient population, including communications between patients and providers?

Response: The PET service will be available to all patients. SRMC is contracted with all existing TennCare MCOs in the area, and SRMC intends to continue its participation in all TennCare MCOs when the new MCO contracts are implemented in 2015.

3. The State's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the State's health care system.

- a. How will this proposal lower the cost of health care?
- b. How will this proposal encourage economic efficiencies?
- c. What information will be made available to the community that will encourage a competitive market for health care services?

Response: This project achieves economic efficiency because it makes use of an existing building on an existing outpatient campus in order to provide the benefits of enhanced convenience and accessibility for advance imaging technology for cancer patients. The project will require only minimal additional staffing.

4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.

- a. How will this proposal help health care providers adhere to professional standards?

- b. How will this proposal encourage continued improvement in the quality of care provided by the health care workforce?

Response: The project contributes to quality of care by making state-of-the-art imaging for cancer patients more accessible, thus increasing the possibility of early diagnosis and enhancing treatment planning. SMRC's commitment to quality care is evidenced by its designation by the Joint Commission as a Top Performer in Key Quality Measures.

5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.

- a. How will this proposal provide employment opportunities for the health care workforce?

- b. How will this proposal complement the existing Service Area workforce?

Response: This project will require only 1 nuclear medicine technologist FTE, and thus will not have a material effect on the health care workforce.

- b. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9 of the Guidelines for Growth) here.

Response: The PET criteria in the State Health Plan are addressed as follows:

PET Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

Response: SRMC does not project volumes that will achieve the minimums in this criterion. SRMC notes, however, that there is a need for the service in the area, and the project is financially viable. Most patients in the region who need PET scans currently obtain the service in Nashville, approximately 30 miles from Gallatin. The availability of PET services at Sumner Station will alleviate the travel burden on cancer patients. The need for PET services in community is further supported by the fact that the cancer incidence rates in Sumner and Macon counties are higher than the statewide average. Based on information in the report titled Cancer in

Tennessee 2005-2009 published in 2013 by the Division of Policy, Planning and Assessment, Tennessee Department of Health, the following information is relevant:

- *For the period 2005-2009, Tennessee had the 16th highest cancer incidence rate in the country and the 6th highest cancer mortality rate.*
- *Tennessee's cancer incidence rate for the period was 476.8 per 100,000.*
- *Sumner County's cancer incidence rate for the period was 487.6 per 100,000, 2.3% higher than the Tennessee rate*
- *Macon County's cancer incidence rate for the period was 554 per 100,000, 16% higher than the Tennessee rate.*

Given that cancer occurs with more frequently in the service area than the statewide average, it is important that state of the art cancer diagnostic resources be conveniently available.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

Response: *Not applicable.*

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: *The proposal is cost-effective, because it makes use of an existing building on an existing outpatient campus. A part-time mobile unit was determined not to be advantageous, because the part-time availability would compromise availability and convenience.*

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

Response: *Not applicable.*

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures/day x 50 days/year = 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

Response: Not applicable. The proposed unit is the first PET unit in the service area.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

Response: FDA approval is documented at Attachment B.II.,E.,1.

- b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Response: The applicant will comply with all applicable standards. See Attachment C., Economic Feasibility -1. In addition, the PET facility will be operated under the same radiation safety standards set forth in SRMC's radiation safety manual.

- c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

Response: The PET center will be licensed and operated as part of SRMC and thus subject to the same emergency management plan and procedures that otherwise apply SRMC. A patient at the PET center who has a medical emergency will be transported by ambulance to SRMC.

- d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

Response: Physicians who refer patients to SRMC for PET procedures will have no financial interest in SRMC or the PET, and PET procedures will be performed on only those patients for whom PET is determined to be medically necessary in the independent medical judgment of the referring physicians. In addition, SRMC has developed draft protocols, a copy of which is attached at Attachment C., Need – PET Standards, item 6.d.

- e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board

of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Response: *The PET service will be under the medical direction of Dr. Glen Nabors, a board certified radiologist with Sumner Radiology, PC. Other radiologists in Sumner Radiology are also qualified to interpret PET scans. The CVs of Dr. Nabors and the other physicians who will interpret PET scans are attached at Attachment C, Need-PET Standards, item 6.e.*

SRMC already has applicable radiological permits from the Division of necessary for existing CT services. SRMC has made preliminary inquiry at the Division regarding a radioactive materials license for the PET at the Sumner Station campus, and it is confident that it will have no difficulty obtaining the appropriate license for the PET unit.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Response: *The proposed PET will be operated by SRMC as part of the hospital, and Dr. Nabors is an active member of SRMC's staff.*

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

Response: *SRMC will submit file its equipment registry reports timely.*

8. In light of Rule 0720-4-.01(1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;
- c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or
- d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Response: SRMC believes it should receive special consideration under this criterion for several reasons:

- SRMC has long history as a participating provider in the TennCare program and contracting with all MCOs serving the region.
 - As previously noted, the incidence of cancer in Sumner and Macon counties is higher than the statewide average. The incidence rate in Sumner County is 2.3% higher than the statewide rate and the incidence rate in Macon County is 16% higher than the statewide rate. These higher incidence rates emphasize the need for better access in the community to cancer diagnosis and treatment capabilities.
 - All of Macon County and part of Sumner County are designated as medically underserved by the United States Health Resources and Administration.
 - PET service does not exist in the area, and the project is financially viable.
- c. Applications that include a Change of Site for a proposed new health care institution (one having an outstanding and unimplemented CON), provide a response to General Criterion and Standards (4)(a-c) of the Guidelines for Growth.

Response: Not applicable.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

Response: SRMC's long-range plan includes the intention to maintain and upgrade services and technology to meet community expectations for modern health care. This project is consistent with this plan because it will bring to the community state-of-the-art imaging for the diagnosis and treatment of cancer.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. **Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).**

Response: SRMC's believes its primary service area for PET service will be the same as its service area for its existing radiation therapy, specifically Sumner and Macon counties. From 2010-2012, approximately 84% of SRMC's radiation therapy patients came from these two counties. SRMC expects a similar proportion of its PET patients will come from these counties. A map showing the service area is attached as Attachment C., Need - 3.

4. A. 1) Describe the demographics of the population to be served by this proposal.

Response: See demographic information at Attachment C. Need – 4.A.(1).

- 2) Using population data from the Department of Health, enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau, please complete the following table and include data for each county in your proposed service area:

Demographic Variable/ Geographic Area	Sumner County	Macon County	Service Area Total	State of TN Total
Total Population – Current Year 2014	172,282	23,188	195,470	6,588,698
Total Population – Projected Year 2016	177,876	23,654	201,530	6,740,579
Total Population - % change	3.25%	2%	3.1%	2.3%
*Target Population – Current Year	25,164	3,647	28,811	981,984
*Target Population – Projected Year	27,389	3,896	31,285	1,069,460
Target Population - % Change	8.8%	6.8%	8.6%	8.9%
Target Population – Projected Year as % of Total	15.4%	16.5%	15.5%	15.9%
Median Age	38.7	38.3		38
Median Household Income	\$55,560	\$35,452		\$44,140
TennCare Enrollees	24,135	6,061	30,196	1,241,028
TennCare Enrollees as % of Total	14%	26%	15.4%	18.8%
Persons Below Poverty Level	16,260	5,295	21,555	1,129,610
Persons Below Poverty Level as % of Total	9.8%	23.5%	11.4%	17.3%

**Target Population is 65+ per application instructions. Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics; TennCare Bureau; U.S. Census Bureau.*

- B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Response: SRMC is contracted with all TennCare MCOs and the new facility will thus be available to all TennCare patients. Cancer disproportionately affects elderly patients, and cancer patients in the region must travel to Nashville in order to get a PET scan. The PET service proposed by SRMC will make the technology more accessible to all patients in the service area.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc. Projects including surgery should report the number of cases and the average number of procedures per case.

Response: There are no approved but unimplemented CONs in the service area for PET service.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization through the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

Response:

	2011	2012	2013	Year 1	Year 2
SRMC				241	337

SRMC currently operates the only radiation therapy service in Sumner and Macon counties. Approximately, 90% of SRMC's radiation therapy volume is from Sumner and Macon counties, and SRMC has approximately 49% of the radiation therapy market from Sumner and Macon counties. The Applicant assumes that its patient origin and market share for PET will be similar to its radiation therapy patient origin and market share. Based on information from the Agency's equipment registry provided by Alecia Craig, the residents of Sumner and Macon counties in the period 2011-2013 received an average of 620 PET scans per year. For its PET service, SRMC assumes in year 1 it will serve 35% of the PET patients from Sumner and Macon counties and these patients will be 90% of its total PET volume for the year, and in year 2 it will serve 49% of the PET patients from Sumner and Macon counties and these patients will be 90% of total PET volumes. The projections set forth above are based on these assumptions.

ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
 - All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
 - The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
 - The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
 - For projects that include new construction, modification, and/or renovation; documentation must be provided from a licensed architect or construction professional that support the estimated construction costs. Please provide a letter that includes:
 - 1) a general description of the project;

- 2) estimate of the cost to construct the project to provide a physical environment, according to applicable federal, state and local construction codes, standards, specifications, and requirements; and
- 3) attesting that the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements including the most recent AIA Guidelines for Design and Construction of Hospital and Health Care Facilities.

Response: Architect letter attached at Attachment C., Economic Feasibility - 1.

PROJECT COSTS CHART

September 29, 2014
11:40am

A. Construction and equipment acquired by purchase:	
1. Architectural and Engineering Fees	<u>\$75,000</u>
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	<u>\$47,000</u>
3. Acquisition of Site	<u> </u>
4. Preparation of Site	<u> </u>
5. Construction Costs	<u>\$460,000</u>
6. Contingency Fund	<u>\$115,000</u>
7. Fixed Equipment (Not included in Construction Contract)	<u>\$1,698,228</u>
8. Moveable Equipment (List all equipment over \$50,000)	<u>\$486,134</u>
	<u>(no items over \$50,000)</u>
9. Other (Specify) _____	<u> </u>
B. Acquisition by gift, donation, or lease:	
1. Facility (inclusive of building and land)	<u> </u>
2. Building only	<u> </u>
3. Land only	<u> </u>
4. Equipment (Specify) _____	<u> </u>
5. Other (Specify) _____	<u> </u>
C. Financing Costs and Fees:	
1. Interim Financing	<u> </u>
2. Underwriting Costs	<u> </u>
3. Reserve for One Year's Debt Service	<u> </u>
4. Other (Specify) _____	<u> </u>
D. Estimated Project Cost (A+B+C)	<u>\$2,881,362</u>
E. CON Filing Fee	<u>\$6,483</u>
F. Total Estimated Project Cost (D+E)	<u> </u>
TOTAL	<u>\$2,887,845</u>

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (**Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.**)

- ☐ A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ C. General obligation bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting.
- ☐ D. Grants--Notification of intent form for grant application or notice of grant award; or
- ☒ E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- ☐ F. Other--Identify and document funding from all other sources.

Response: Funding confirmation attached at *Attachment C, Economic Feasibility -2.*

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

Response: According to the HSDA's website, the 2011-2013 construction costs for hospitals in the 3rd quartile were \$249.00 per sq. ft. for renovation. The construction costs for the project are projected to be \$322.80 per sq. ft. for renovation, which is reasonable as confirmed by the project architect.

4. Complete Historical and Projected Data Charts on the following two pages--**Do not modify the Charts provided or submit Chart substitutions!** Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the **Proposal Only** (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should also include any management fees paid by agreement to third party entities not having common ownership with the applicant. Management fees should not include expense allocations for support services, e.g., finance, human resources, information technology, legal, managed care, planning marketing, quality assurance, etc. that have been consolidated/centralized for the subsidiaries of a parent company.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Response: Average gross charge per treatment is \$7,500, average deduction will be \$5,595 and average net charge will be \$1,905.

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HISTORICAL DATA CHART

SUPPLEMENTAL- 1

Give information for the last *three* (3) years for which complete data are available for the last September 25, 2014 agency. The fiscal year begins in January (Month). 4:05pm

	Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
A. Utilization Data (Adjusted Admissions)	<u>14,330</u>	<u>15,146</u>	<u>15,967</u>
B. Revenue from Services to Patients			
1. Inpatient Services	<u>\$147,022,000</u>	<u>\$178,940,000</u>	<u>\$222,998,000</u>
2. Outpatient Services	<u>162,648,000</u>	<u>196,626,000</u>	<u>221,909,000</u>
3. Emergency Services	<u>34,577,000</u>	<u>41,567,000</u>	<u>52,971,000</u>
4. Other Operating Revenue (Specify) _____	<u>2,312,000</u>	<u>2,145,000</u>	<u>1,055,000</u>
Gross Operating Revenue	<u>\$346,559,000</u>	<u>\$419,278,000</u>	<u>\$498,923,000</u>
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	<u>\$221,391,000</u>	<u>\$286,650,000</u>	<u>\$351,127,000</u>
2. Provision for Charity Care	<u>8,248,000</u>	<u>8,372,000</u>	<u>9,247,000</u>
3. Provisions for Bad Debt	<u>14,402,000</u>	<u>18,846,000</u>	<u>24,538,000</u>
Total Deductions	<u>\$244,041,000</u>	<u>\$313,868,000</u>	<u>\$384,912,000</u>
NET OPERATING REVENUE	<u>\$102,518,000</u>	<u>\$105,410,000</u>	<u>\$114,011,000</u>
D. Operating Expenses			
1. Salaries and Wages	<u>\$ 45,972,000</u>	<u>\$ 45,996,000</u>	<u>\$ 48,697,000</u>
2. Physician's Salaries and Wages	<u> </u>	<u> </u>	<u> </u>
3. Supplies	<u>16,054,000</u>	<u>16,662,000</u>	<u>17,116,000</u>
4. Taxes	<u>6,945,000</u>	<u>6,959,000</u>	<u>10,112,000</u>
5. Depreciation	<u>9,397,000</u>	<u>9,640,000</u>	<u>8,408,000</u>
6. Rent	<u>507,000</u>	<u>171,000</u>	<u>618,000</u>
7. Interest, other than Capital	<u> </u>	<u> </u>	<u> </u>
8. Management Fees:			
a. Fees to Affiliates	<u>3,741,000</u>	<u>4,090,000</u>	<u>4,408,000</u>
b. Fees to Non-Affiliates	<u> </u>	<u> </u>	<u> </u>
9. Other Expenses – Specify on Page 21	<u>14,961,000</u>	<u>17,589,000</u>	<u>18,246,000</u>
Total Operating Expenses	<u>\$ 97,577,000</u>	<u>\$101,106,000</u>	<u>\$107,605,000</u>
E. Other Revenue (Expenses) – Net (Specify) _____	<u>\$ </u>	<u>\$ </u>	<u>\$ </u>
NET OPERATING INCOME (LOSS)	<u>\$ 4,941,000</u>	<u>\$ 4,304,000</u>	<u>\$ 6,406,000</u>
F. Capital Expenditures			
1. Retirement of Principal	<u>\$ </u>	<u>\$ </u>	<u>\$ </u>
2. Interest	<u> </u>	<u> </u>	<u> </u>
Total Capital Expenditures	<u>\$ </u>	<u>\$ </u>	<u>\$ </u>
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	<u>\$ 4,941,000</u>	<u>\$ 4,304,000</u>	<u>\$ 6,406,000</u>

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year <u>2016</u>	Year <u>2017</u>
A. Utilization Data (PET Scans)	<u>241</u>	<u>337</u>
B. Revenue from Services to Patients		
1. Inpatient Services	\$ <u> </u>	\$ <u> </u>
2. Outpatient Services	<u>1,808,000</u>	<u>2,528,000</u>
3. Emergency Services	<u> </u>	<u> </u>
4. Other Operating Revenue (Specify) <u> </u>	<u> </u>	<u> </u>
Gross Operating Revenue	\$ <u>1,808,000</u>	\$ <u>2,528,000</u>
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	\$ <u>1,245,000</u>	\$ <u>1,741,000</u>
2. Provision for Charity Care	<u>38,000</u>	<u>54,000</u>
3. Provisions for Bad Debt	<u>65,000</u>	<u>91,000</u>
Total Deductions	\$ <u>1,348,000</u>	\$ <u>1,886,000</u>
NET OPERATING REVENUE	\$ <u>459,000</u>	\$ <u>642,000</u>
D. Operating Expenses		
1. Salaries and Wages	\$ <u>54,000</u>	\$ <u>54,000</u>
2. Physician's Salaries and Wages	<u> </u>	<u> </u>
3. Supplies	<u>75,000</u>	<u>121,000</u>
4. Taxes	<u>11,000</u>	<u>42,000</u>
5. Depreciation	<u>259,000</u>	<u>259,000</u>
6. Rent	<u> </u>	<u> </u>
7. Interest, other than Capital	<u> </u>	<u> </u>
8. Management Fees	<u> </u>	<u> </u>
a. Fees to Affiliates	<u> </u>	<u> </u>
b. Fees to Non-Affiliates	<u> </u>	<u> </u>
9. Other Expenses – Specify on Page 23 <u> </u>	<u>42,000</u>	<u>101,000</u>
Total Operating Expenses	\$ <u>441,000</u>	\$ <u>577,000</u>
E. Other Revenue (Expenses) – Net (Specify) <u> </u>	\$ <u> </u>	\$ <u> </u>
NET OPERATING INCOME (LOSS)	\$ <u>18,000</u>	\$ <u>65,000</u>
F. Capital Expenditures		
1. Retirement of Principal	\$ <u> </u>	\$ <u> </u>
2. Interest	<u> </u>	<u> </u>
Total Capital Expenditures	\$ <u> </u>	\$ <u> </u>
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$ <u>18,000</u>	\$ <u>65,000</u>

HISTORAL DATA CHART – OTHER EXPENSES

September 25, 2014
4:05pm

<u>OTHER EXPENSES CATEGORIES</u>	Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
1. Professional Fees	\$ <u>2,564,000</u>	\$ <u>2,597,000</u>	\$ <u>3,472,000</u>
2. Contract Services	<u>4,833,000</u>	<u>5,323,000</u>	<u>5,291,000</u>
3. Repairs and Maintenance	<u>3,485,000</u>	<u>3,485,000</u>	<u>3,854,000</u>
4. Utilities	<u>2,583,000</u>	<u>2,584,000</u>	<u>2,665,000</u>
5. Insurance	<u>(181,000)</u>	<u>843,000</u>	<u>604,000</u>
6. Investment Income	<u>(89,000)</u>		
7. Other (Marketing, Recruiting, etc.)	<u>1,766,000</u>	<u>2,757,000</u>	<u>2,360,000</u>
Total Other Expenses	\$ <u>14,961,000</u>	\$ <u>17,589,000</u>	\$ <u>18,246,000</u>

PROJECTED DATA CHART – OTHER EXPENSES

<u>OTHER EXPENSES CATEGORIES</u>	Year <u>2017</u>	Year <u>2018</u>
1. Professional Fees	\$ _____	\$ _____
2. Contract Services	_____	_____
3. Repairs and Maintenance	_____	<u>59,000</u>
4. Utilities	<u>12,000</u>	<u>12,000</u>
5. Marketing, recruiting, etc.	<u>30,00</u>	<u>30,000</u>
6.	_____	_____
7.	_____	_____
Total Other Expenses	\$ <u>42,000</u>	\$ <u>101,000</u>

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Response: The average gross charge for PET scans will be \$7,500 per scan. This is a new service for SRMC, so it will not impact existing patient charges.

- B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response: Based on 2013 information from the Health Services and Development Agency's Equipment Registry, SRMC's proposed charge will be slightly over the 3rd Quartile for the state, which is \$7,307.21. The median charge from the Equipment Registry is \$4,834.25. A comparison of SRMC's proposed charge and the Medicare allowable by procedure follows:

CPT	Description	SRM Change	Medicare Allowable
78811	PET, 1H area	\$7,500	\$1,056.12
78812	PET, skull-thigh	\$7,500	\$1,056.12
78813	PET, full body	\$7,500	\$1,056.12
78814	PET, w/ct ltd	\$7,500	\$1,056.12
78815	PET, w/ct skull-thigh	\$7,500	\$1,056.12
78816	PET, w/ct full body	\$7,500	\$1,056.12

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness; how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Response: As indicated in the Projected Data Chart, the project will achieve positive financial results in the first year.

8. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Response: SRMC is contracted with all TennCare MCOs that serve the region, and it is committed to do so in the future. Gross revenues from TennCare in year 1 are projected to be \$120,000 (6.63%) and gross revenues from Medicare are projected to be \$816,000 (45.13%).

9. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end

of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-9.

Response: SRMC does have an audited financial statement, but it's 2013 unaudited balance sheet and income statement are attached under Attachment C, Economic Feasibility - 9.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Response: Since SRMC already owns the building at Sumner Station, and in light of the outpatient services and medical offices that are on site at Sumner Station, SRMC did not consider alternative sites. Any other site would have been substantially more expensive because of the need to purchase land and construct a building or the need to lease space.

Another alternative would have been to contract with a mobile service on a part-time basis. SRMC determined that investing in a fixed PET unit as the superior alternative, because the fixed unit provides maximum availability and flexibility for patients and the fixed service achieves a positive financial result.

- b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

Response: This project does not involve new construction, but makes cost-effective use of an existing building.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

Response: Lists of managed care contracts and provider contracts are attached under Attachment C, Contribution to the Orderly Development of Health Care – 1.

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

Response: This project will have only positive effects, because of improved patient convenience. In addition, SRMC believes the presence of PET service in the community will enhance the confidence of Sumner and Macon county residents that they can receive first-class treatment in their community rather traveling to Nashville. PET service does not currently exist in the market, so the project will not affect any other provider in the service

area. The patient benefits from PET services being available at Sumner Station are confirmed by the letter of support from Tennessee Oncology attached at Attachment C., Orderly Development of Health Care – 2.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Response: The PET service will require only 1 nuclear medicine technologist FTE:

<u>Position</u>	<u>FTE</u>	<u>Salary</u>
Nuclear Medicine Technologist	1	\$54,000

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities licensing requirements.

Response: The PET service will require only 1 addition to clinical staff. SRMC foresees no difficulty in filling this position.

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

Response: SRMC has reviewed and understands licensing and certification requirements applicable to its medical and clinical staff.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

Response: SRMC has an agreement with Austin Peay University, under which SRMC is a clinical training site for radiation therapy technologists. The Sumner Station campus is covered by this agreement.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Substance Abuse Services, the Department of Intellectual and Developmental Disabilities, and/or any applicable Medicare requirements.

Response: SRMC has viewed and understands the licensing requirements of the Department of Health.

- (b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure: Tennessee Department of Health

Accreditation: *Joint Commission. SRMC's cancer program is accredited by the American College of Surgeons Commission on Cancer Care.*

- (c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Response: *SRMC is accredited by the Joint Commission and its cancer program is accredited by the American College of Surgeons Commission on Cancer Care. A copy of SRMC's license from the Tennessee Department of Health and Joint Commission accreditation are attached under Attachment C, Contribution to the Orderly Development of Health Care – 7(c).*

- (d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction. Please also discuss what measures the applicant has or will put in place to avoid being cited for similar deficiencies in the future.

Response: *A copy of SRMCs' most recent survey and the plan of correction relative to the survey is attached under Attachment C, Contribution to the Orderly Development of Health Care -7(d).*

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Response: *There are no judgments or orders to be reported in response to this item.*

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

Response: *There are no judgments to be reported in response to this item.*

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Response: *SRMC will provide to the Health Services and Development Agency the information described in this item.*

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

Response: Proof of Publication Attached.

NOTIFICATION REQUIREMENTS

(Applies only to Nonresidential Substitution-Based Treatment Centers for Opiate Addiction)

Please note that Tennessee Code Annotated 68-11-1607(c)(3) states that "...Within ten (10) days of filing an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located, the member of the House of Representatives and the Senator of the General Assembly representing the district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential substitution based treatment center for opiate addiction has been filed with the agency by the applicant."

Please provide this documentation.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

0101764279

Affidavit of Publications

SEP 16 12 PM 2014

Newspaper: THE TENNESSEAN**State Of Tennessee****TEAR SHEET
ATTACHED****Account Number:** 540358**Advertiser:** BUTLER, SNOW, O'MARA, STEVENS**RE:** Sumner Regional Medical Center - CERTIFII, R Perry Sales Assistant for theabove mentioned newspaper, hereby certify that the attached
advertisement appeared in said newspaper on the following dates:✓
9/10/2014R PerrySubscribed and sworn to me this 10 day of Sept, 2014Sela Bates
NOTARY PUBLIC

0101764279

**NOTIFICATION OF INTENT TO APPLY FOR A
CERTIFICATE OF NEED**

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that:

Sumner Regional Medical Center, a hospital owned by: Sumner Regional Medical Center, LLC with an ownership type of limited liability company intends to file an application for a Certificate of Need to initiate positron emission tomography ("PET") service at its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard, Gallatin, Tennessee. The project will require build-out of approximately 1,425 square feet of existing space and the purchase of G.E. Discovery PET/CT Imaging System. The total project cost is approximately \$2,687,896. The project does not involve a change in licensed bed capacity or the initiation of any service requiring a certificate of need, except positron emission tomography.

The anticipated date of filing the application is: September 15, 20 14

The contact person for this project is Dan Elrod, Attorney, who may be reached at: Butler Snow LLP, 150 3rd Avenue South, Suite 1600, Nashville, TN 37201 615 / 651-6702

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development
Agency
Andrew Jackson Building, 9th floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

6D WEDNESDAY, SEPTEMBER 10, 2014

★ **business**

THE TENNESSEAN

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
2. If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph*, please state below any request for an extended schedule and document the "good cause" for such an extension.

Form HF0004
Revised 08/01/2012
Previous Forms are obsolete

September 25, 2014
4:05pm

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. §68-11-1609(c): Dec. 2014

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

Phase	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed		Dec. 2014
2. Construction documents approved by the Tennessee Department of Health	90	April. 2015
3. Construction contract signed	90	April 2015
4. Building permit secured	120	May 2015
5. Site preparation completed	N/A	N/A
6. Building construction commenced	145	May 2015
7. Construction 40% complete	210	July 2015
8. Construction 80% complete	270	Sept. 2015
9. Construction 100% complete (approved for occupancy)	330	Nov. 2015
10. *Issuance of license	330	Nov. 2015
11. *Initiation of service	345	Dec. 2015
12. Final Architectural Certification of Payment	345	Dec. 2015
13. Final Project Report Form (HF0055)	420	Feb. 2016

* For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

AFFIDAVIT

STATE OF Tennessee
 COUNTY OF Davidson

Dan H. Elrod, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

[Signature]
 SIGNATURE/TITLE

Sworn to and subscribed before me this 15th day of Sept., 2014 a Notary
 (Month) (Year)
 Public in and for the County/State of Davidson County Tennessee.

Sharron C. Couch
 NOTARY PUBLIC

My commission expires 3-8
 (Month/Day)



My Commission Expires MAR. 8, 2018

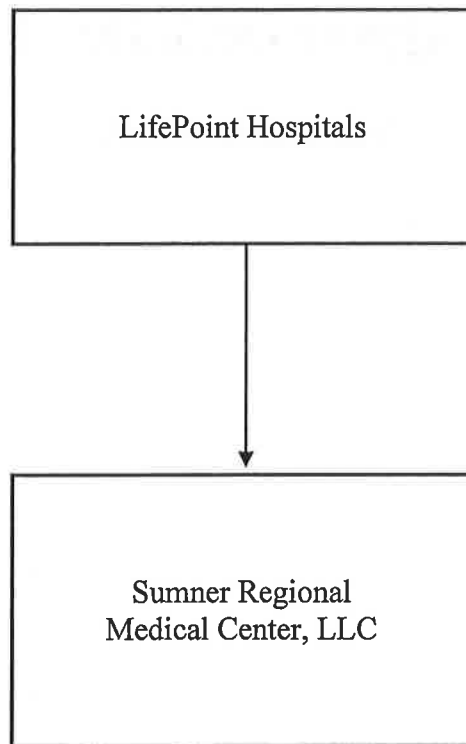
Attachment A, Item 3

Organizational Documents

Attachment A, Item 4

Organizational Chart

9/2/14 4:23:35



Note: This chart shows only the entities pertinent to the application. It is not possible to produce a chart that includes all 58 hospitals operated by LifePoint, but a list of LifePoint hospitals in Tennessee is attached.

LifePoint Hospitals in Tennessee

Livingston Regional Hospital
315 Oak Street
Livingston, TN 38570

Riverview Regional Medical Center
158 Hospital Dr
Carthage, TN 37030

Southern Tennessee Regional Healthy System at Lawrenceburg
1607 South Locust Ave
Lawrenceburg, TN 38464

Southern Tennessee Regional Health System at Sewanee
1260 University Ave
Sewanee, TN 37375

Southern Tennessee Regional Health System at Pulaski
1265 East College Street
Pulaski, TN 38478

Southern Tennessee Regional Health System at Winchester
185 Hospital Rd
Winchester, TN 37398

Starr Regional Medical Center
1114 West Madison Ave
Athens, TN 37303

Starr Regional Medical
886 Highway 411 North
Etowah, TN 37331

Sumner Regional Medical Center
555 Hartsville Pike
Gallatin, TN 37066

Trousdale Medical Center
500 Church Street
Hartsville, TN 37074

Attachment B, III(A)**Plot Plan**

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SITE IMPROVEMENT AREA
PROJECT LOCATION

24.57 ACRES

BIG STATION CAMP ROAD

VIETNAM VETERANS PARKWAY
STATE ROUTE 386

RADIATION ONCOLOGY UNIT at SUMNER STATION for SUMNER REGIONAL MEDICAL CENTER



GALLATIN, TN 37066

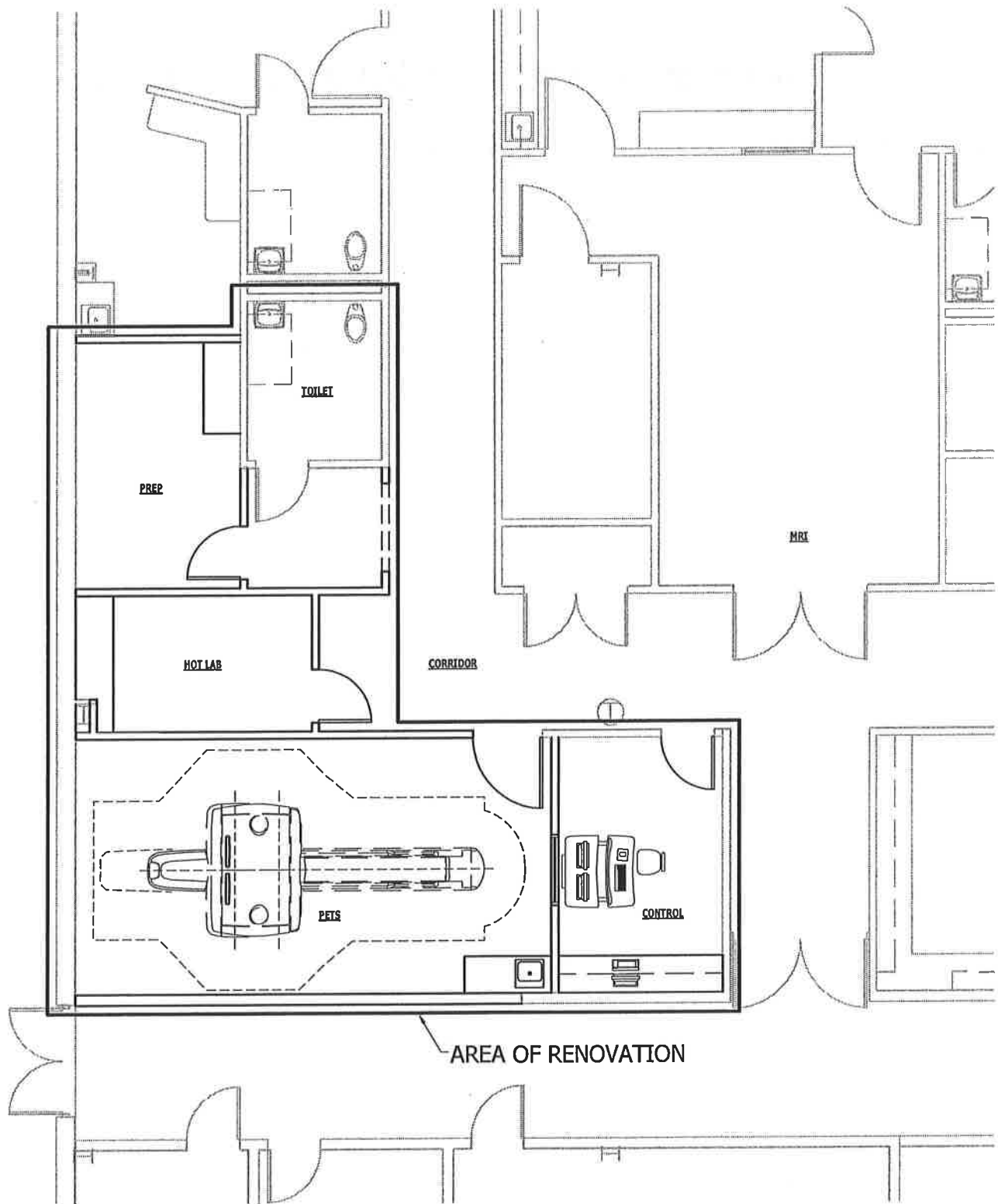
03/07/2014 - C.O.N. SUBMITTAL - NOT FOR CONSTRUCTION

HINSON MILLER KICKIRILLO ARCHITECTS PLLC

SITE IMPROVEMENT=37,000 SF

Attachment B, IV

Floor Plan



PET SCANNER at SUMNER STATION for SUMNER REGIONAL MEDICAL CENTER

GALLATIN, TENNESSEE
AUGUST 15, 2014
HINSON MILLER KICKIRILLO ARCHITECTS, PLLC
C.O.N. SUBMITTAL - NOT FOR CONSTRUCTION



Attachment C, Need – PET Standards, item 6.d.

Protocols

Imaging Orders for Positron Emission Tomography (PET)/Computed Tomography (CT)

Scope: Positron Emission Tomography (PET)/Computed Tomography (CT)

Purpose: To provide guidelines for PET/CT procedures.

Policy: All requests, exam protocols and reports related to PET/CT procedures must be in compliance with current appropriate use criteria for PET/CT studies published periodically by the American College of Radiology. All exam protocols must be approved by the Medical Director of Radiology.

Procedure:

- PET/CT procedure appointments shall be scheduled through the Sumner Regional Medical Center (SRMC) central scheduling department.
- PET/CT procedures will be completed according to a signed order provided by a referring physician. All orders must include reason for examination, diagnosis, physician's signature, date and time.
- All PET/CT reports will be read by board certified radiologists with appropriate Nuclear Medicine and PET/CT training.
- PET/CT reports will be available via hospital information system and images retained in PACS.
- All laboratory testing will be completed and all orders will be verified prior to Fluorodeoxyglucose (FDG) injection.
- The processes, policies and procedures related to PET/CT patient testing shall be monitored for accuracy and compliance.

Attachment C, Need – PET Standards, item 6.e.

Physician CVs

Glenn F. Nabors, Jr.
620 Hartsville Pike
Gallatin, TN 37066
(615) 452-9470 Glenn.Nabors@lpnt.net

- Certifications** American Board of Radiology
- Effective June 1994
- Fellowship** University of South Florida Tampa, FL
- Neuroradiology 1994-1995
- Residency** Methodist Hospital Memphis, TN
- Diagnostic Radiology 1990-1994
 - Transitional Intern 1989-1990
- Education** UT College of Medicine Memphis, TN
- Doctor of Medicine June 1989
- Tennessee Technological University Cookeville, TN
- Electrical Engineering June 1984
- Employment** Sumner Radiology PC, Gallatin, TN
December 30, 1996 to Present
- East Pasco Radiology Associates, Zephyrhills, FL
July 1995 – December 1996
- Licensure** Tennessee 1990

Elton Benjamin Greene
 229 Village at Vanderbilt, Nashville, TN 37212
 email: ebengreene@gmail.com
 phone: (901) 233-1392

Certifications	ABR Board Certification in Diagnostic Radiology <ul style="list-style-type: none"> • Effective July 1, 2012
Fellowship	Vanderbilt Neuroradiology Fellowship <ul style="list-style-type: none"> • Neuroradiology Fellow, July 2012-Present
Residency	UT/Methodist Healthcare Radiology Residency, Memphis, TN <ul style="list-style-type: none"> • Diagnostic Radiology Resident, 2008-present • Transitional Intern, 2007-2008
Education	University of Tennessee Health Sciences Center (UTHSC), Memphis, TN <ul style="list-style-type: none"> • Doctor of Medicine, 2007 Emory University, Atlanta, GA <ul style="list-style-type: none"> • BA in Religion and Psychology, 1998
Honors	Summit Alumni Merit Scholarship, UTHSC <ul style="list-style-type: none"> • Full tuition, four year medical school scholarship.
Experience	Education Specialist, Philadelphia High School Partnership, 1998-2001 <ul style="list-style-type: none"> • Facilitated teams of high school students creating service-learning volunteer projects in the Philadelphia, PA metro area.
Publication	Cohen HL, Greene EB, Boulden TP. The Vomiting Neonate or Young Infant. Ultrasound Clinics January 2010; Volume 5, Issue 1: pages 97-112.
Activities	President, Council for Area and International Outreach, UTHSC <ul style="list-style-type: none"> • Oversaw \$16,000 per year in grants for UT medical students traveling abroad and addressing local health disparities in Memphis. Varsity Swimming, Emory University, 1995-1997
Interests	Photography
Membership	RSNA, member since 2008 ACR, member since 2008

MICHAEL BAZZANI

620 Harlsville Pike Gallatin, TN 37066 | (615) 452 9470

EDUCATION | UNIVERSITY OF ILLINOIS, SPRINGFIELD IL
MEDICAL SCHOOL AUGUST 1999 TO MAY 2003
UNIVERSITY OF ILLINOIS, SPRINGFIELD IL
INTERNSHIP JULY 2003 TO JUNE, 2004
UNIVERSITY OF ILLINOIS, SPRINGFIELD IL
RESIDENCY IN RADIOLOGY
UNIVERSITY OF MIAMI, MIAMI, FL
FELLOWSHIP MRI

EMPLOYMENT | Sumner Radiology PC, Gallatin, TN
July, 2009 to Present

University Of Miami, Miami, FL

July, 2008 to June, 2009

University of Illinois, Chicago, IL

July, 2004 to June, 2008

BOARD CERTIFIED | American Board of Radiology 6/3/2008
IN RADIOLOGY

CURRICULUM VITAE WILLIAM LEE KRAFT, MD**PERSONAL INFORMATION****Social Security Number** 371 46 9908**Personal Address** 2325 Nashville Pike Apt. 902
Gallatin, TN 37066**Birth Date** Dec 24, 1956**Birth Place** Detroit, MI**Citizenship** United States**EDUCATION****High School** Cranbrook School
Bloomfield Hills, MI
Graduated with Honors, 1974**Undergraduate** University of Michigan
Ann Arbor, MI
BA in Zoology with High Honors, 1978**Medical School** University of California at Los Angeles
MD, 1982**Internship** LDS Hospital
Salt Lake City, UT
Internal Medicine
June 1982 - June 1983**Residency** Los Angeles County/ University of Southern
California Medical Center
Los Angeles, CA
July 1983 to June 1987**Fellowship** Angiography/Interventional Radiology
University of Texas M.D. Anderson Cancer Center
Houston, TX
July 1987 - June 1988

CURRICULUM VITAE WILLIAM LEE KRAFT, MD page 2**LICENSURE**

California	Certificate #G51739
Florida	License #ME53465
Tennessee	License #2884533

BOARD CERTIFICATION

Diplomate National Board of Medical
Examiners 1983

Diplomate American Board of Radiology
Diagnostic Radiology 1987

Diplomate American Board of Radiology
Certificate of Added Qualification in
Neuroradiology 1996

HOSPITAL APPOINTMENTS**Medical Staff Membership**

Columbia Dade City Hospital
Dade City, FL
1988 to 1997

Spring Hill Regional Medical Center
Spring Hill, FL
1995 to 2001

Brooksville Regional Medical Center
Brooksville, FL
1995 to 2001

East Pasco Medical Center
Zephyrhills, FL
1988 to 2002

CURRICULUM VITAE WILLIAM LEE KRAFT, MD page 3**Medical Staff Membership (continued)**

**Sumner Regional Medical Center
Gallatin, TN
2002 to present**

**Trousdale Medical Center
Hartsville, TN
2002 to present**

**Macon County General Hospital
Lafayette, TN
2002 to present**

**Smith County Memorial Hospital
Carthage, TN
2002 to present**

**Carthage General Hospital
Carthage, TN
2002 to present**

Board of Trustees

**Columbia Dade City Hospital
Dade City, FL
1993 to 1997**

Chief of Staff

**Columbia Dade City Hospital
Dade City, FL
1996 to 1997**

Medical Director

**Department of Radiology
East Pasco Medical Center
Zephyrhills, FL
1993 to 1998**

Matthew K. Jones

1263 Clark Way
 Palo Alto, CA 94304
 901.258.0389
 mkj1560@gmail.com

Professional Education

Stanford University Medical Center
 Body Imaging Fellowship

Stanford, CA
 2012-2013

Training in all facets of body imaging, including CT, MR, US, image-guided procedures (CT and US), PET/CT, and virtual colonoscopy with additional training in mammography.

American Board of Radiology
 Board Certification, Diagnostic Radiology

2012

University of Tennessee/Methodist Healthcare
 Radiology Residency

Memphis, TN
 2008-2012

Intensive training in all subspecialties of radiology, including mammography (MQSA qualified), nuclear medicine (NRC authorized user), and neuroradiology.

University of Tennessee/Methodist Healthcare
 Transitional Internship

Memphis, TN
 2007-2008

University of Tennessee College of Medicine
 Doctor of Medicine

Memphis, TN
 2003-2007

Vanderbilt University
 Bachelor of Science, Neuroscience

Nashville, TN
 1999-2003

Work Experience

Arkansas Methodist Medical Center
 Adjunct Radiologist

Paragould, AR
 2011-2012

Provided final interpretations of all radiographs, CT, US, and nuclear medicine studies performed during thirteen weekends in a community hospital.

Awards

Vanderbilt University Dean's Select Honors Scholarship (full tuition)
 National Merit Scholarship

1999-2003
 1999

Current Medical Licenses
 California

Professional Memberships

American College of Radiology, Radiologic Society of North America, American Roentgen Ray Society

References

R. Brooke Jeffrey, M.D.
Professor of Radiology, Stanford University
300 Pasteur Dr., Room H1307
Stanford, CA 94305
(650) 723-8463
bjeffrey@stanford.edu

Michael Federle, M.D.
Professor of Radiology, Stanford University
300 Pasteur Dr., Grant Building S-092
Stanford, CA 94305
(650) 721-6411
federle@stanford.edu

Randall Scott, M.D.
Professor of Radiology, University of Tennessee Health Science Center
1030 Jefferson Ave.
Memphis, TN 38104
(901) 577-7466
rascott@uthsc.edu

MICHAEL A. HENCEY
1634 LATIMER LANE
HENDERSONVILLE, TN 37075
(615) 264-9255

EMPLOYMENT: Sumner Radiology
Gallatin, TN Jan 2004 to current

Memorial Hospital, Department of Radiology
Tampa, FL 1994-2003

Consultant for James A. Haley VA Hospital
Tampa, FL 1995-2000

EDUCATION: Fellowship: Neuroradiology
University of South Florida College of Medicine
Tampa, FL 1993-1994

Residency: Diagnostic Radiology Residency
University of South Florida College of Medicine
Tampa, FL 1989-1993

Internship: Internal Medicine Internship
University of South Florida College of Medicine
Tampa, FL 1988-1989

Medical Education: University of South Florida College of
Medicine Tampa, FL 1984-1988

Undergraduate Education: University of Florida
Gainesville, FL 1980-1984 Bachelor of Science, Microbiology

MEMBERSHIP IN RADIOLOGY SOCIETIES:

American Society of Neuroradiology, junior member
Radiological Society of North America
Roentgen Ray
Florida West Coast Radiological Society
President 1997-1998
Vice President 1996-1997

CERTIFICATIONS: Passed parts I, II and III of National Medical Boards
Certified in Diagnostic Radiology from American Board
of Radiology June 1993
Certificate of Added Qualification in Neuroradiology from

American Board of Radiology October 1996

LICENSURE

State of Tennessee Medical License 2003
State of Florida Medical License 1989
DEA Registered 1990

RESEARCH AND WORK RELATED EXPERIENCES:

National Institute of Health Summer Research Grant, summer
1985: Combination Chemotherapy Research: Inhibition
of Mouse Tumor cell Ribonucleotide Reductase by Various
Chemotherapeutic Agents. Department of Biochemistry,
University of South Florida
Prosecution Dissections: Department of Anatomy, summer 1985
Physician Shadow Program: Clinical Nephrology 1985
Judeo Christian Indigent Care Clinic Volunteer 1985
Research Project: MRI Evidence for Cervical Disk Degeneration
After Anterior Cervical Fusions 1988

PUBLICATIONS AND PRESENTATIONS:

Hencey MA, Murtagh FR, Yost JL, "Magnetic Resonance
Imaging of Multiple Sclerosis", Contemporary Diagnostic
Radiology, vol. 16, No. 17, 1993

Altus P, Weissman MS, Hencey MA, "A 73 Year Old Woman
With Confusion, Rigidity and Fever", Hospital Practice,
Pp. 97-98, June 15, 1991

Hencey MA, Murtagh FR, "Measurement of Lumbar Spinal Cord
Cross Sectional Area by CT and MRI: presented at the
Southeast Neuroradiologic Society Meeting, Williamsburg,
VA October 1991

RESIDENCY HONORS AND AWARDS:

Chief Resident 1992-1993

MEDICAL SCHOOL HONORS AND ACTIVITIES:

Honors Grades in Biochemistry, Physiology, Cross Sectional
Anatomy, Medicine Clerkship, Internal Medicine, Acting
Internship, Directed Studies in Radiology
Class Rank: Top 20%
Annual Radiology Student Award 1988
Laennec Award for excellence in Clinical Medicine 1988
Intramural Sports: football, basketball, volleyball, and racquetball

Membership in Societies:

American Medical Student Organization
American Academy of Family Physicians
Florida Academy of Family Physicians
USF Family Practice Student Organization
Southern Medical Association

COLLEGE HONORS AND ACTIVITIES:

College of Liberal Arts and Sciences Honors Program
Honors Organic Chemistry Program
A.E.D. Preprofessional Honor Society
SAMPSON Volunteer Organization, 1980-1984
-Gainesville VA Hospital Emergency Room
-Gainesville Community Convalescence Center
University of Florida Rugby-Football Club
Intramural Sports: football, basketball

LOCUM TENENS: Multiple local outpatient diagnostic centers

PERSONAL: Birthdate: February 10, 1962

Birthplace: Plant City, FL

Marital status: Married

Activities: Biking, scuba diving, racquetball, rugby, and weightlifting,

REFERENCES: Available upon request

320 OLD HICKORY BOULEVARD • UNIT #2807 • NASHVILLE, TN 37221

PHONE (615)500-7990 • E-MAIL BRENT.FRISBIE@VANDERBILT.EDU

BRENT K. FRISBIE, MD

EDUCATION

1995 – 1999	Birmingham – Southern College (BSC)	Birmingham, AL
1999 – 2003	Vanderbilt Medical School	Nashville, TN

PROFESSIONAL EXPERIENCE

July 2003 – June 2004	Baptist Hospital – Nashville, TN
<i>Internship – Medicine</i>	
July 2004 – Present	Vanderbilt University
<i>Residency – Radiology</i>	

PATENTS AND PUBLICATIONS

Surveillance of childhood influenza virus infection: what is the best diagnostic method to use for archival samples?
J Clin Microbiol. 2004 May;42(3):1181-4.

AWARDS RECEIVED

- Amos Christie Scholarship – Vanderbilt Medical School
- *Summa cum laude* with B.S. in Mathematics - BSC
- Acton Award – Highest ranking graduate in Mathematics at BSC
- All American Men's Soccer – BSC

Board Examinations Passed:

- Radiologic Physics – September 2005
- USMLE Step 3 – February 2004
- USMLE Step 2 – November 2002
- USMLE Step 1 – June 2001

JASON ROTH

620 Hartsville Pike Gallatin, TN 37066 | (615) 452-9470

EDUCATION | UNIVERSITY OF TENNESSEE, KNOXVILLE TN

Completed December 2001

University of Tennessee, Memphis, TN

Medical School completed May 2006

Memorial Health, University Medical Center, Savannah, GA

Internship July, 2006 to June, 2007

Baptist Memorial Hospital, Memphis, TN

Residency in Radiology July, 2007 to July 2011

EMPLOYMENT | Sumner Radiology PC, Gallatin, TN

August 2011 to Present

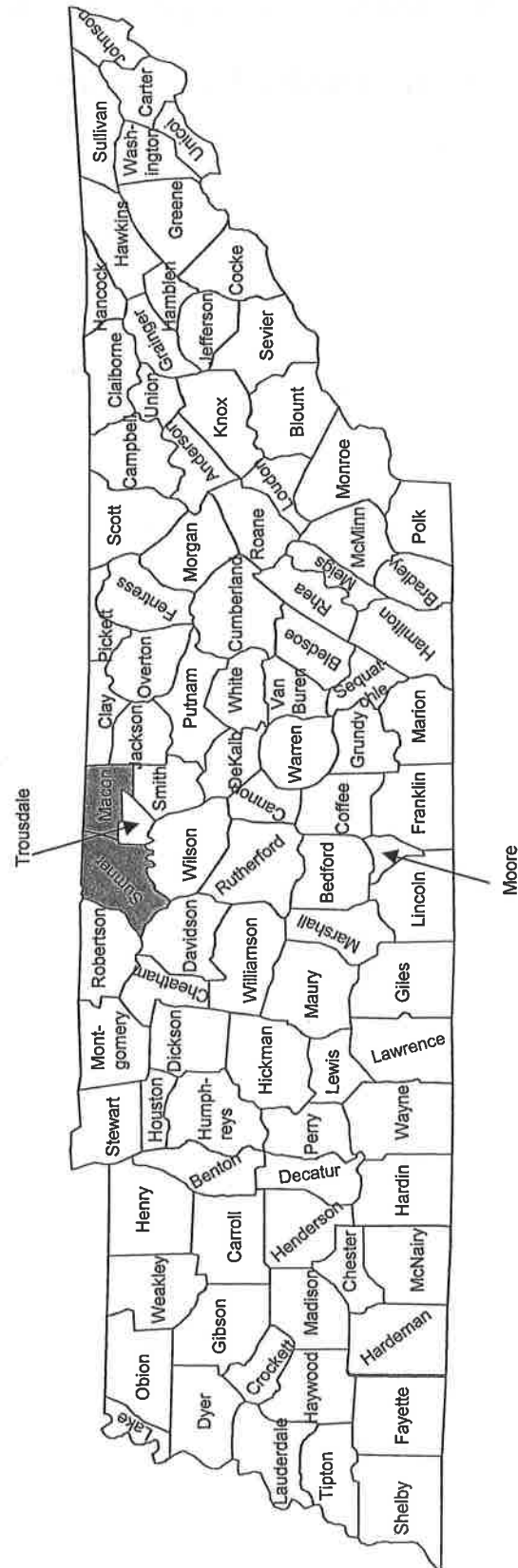
Baptist Memorial Hospital, Memphis, TN

July, 2007 to July, 2011

BOARD CERTIFIED
IN RADIOLOGY | American Board of Radiology 5/25/2011

Attachment C, Need - 3

Service Area Map



Attachment C, Need – 4.A.(1)

Demographic Information

U.S. Department of Commerce

Home Blogs About Us Index A to Z Glossary FAQs

People Business Geography Data Research Newsroom Search Go

State & County QuickFacts

Sumner County, Tennessee

People QuickFacts	Sumner County	Tennessee
Population, 2013 estimate	168,888	6,495,978
Population, 2012 estimate	165,927	6,454,914
Population, 2010 (April 1) estimates base	160,645	6,346,113
Population, percent change, April 1, 2010 to July 1, 2013	5.1%	2.4%
Population, percent change, April 1, 2010 to July 1, 2012	3.3%	1.7%
Population, 2010	160,645	6,346,105
Persons under 5 years, percent, 2012	6.2%	6.3%
Persons under 18 years, percent, 2012	24.6%	23.1%
Persons 65 years and over, percent, 2012	13.8%	14.2%
Female persons, percent, 2012	51.2%	51.2%
White alone, percent, 2012 (a)	90.1%	79.3%
Black or African American alone, percent, 2012 (a)	6.7%	17.0%
American Indian and Alaska Native alone, percent, 2012 (a)	0.3%	0.4%
Asian alone, percent, 2012 (a)	1.2%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	0.1%	0.1%
Two or More Races, percent, 2012	1.6%	1.6%
Hispanic or Latino, percent, 2012 (b)	4.1%	4.8%
White alone, not Hispanic or Latino, percent, 2012	86.5%	75.1%
Living in same house 1 year & over, percent, 2008-2012	83.7%	84.4%
Foreign born persons, percent, 2008-2012	3.4%	4.5%
Language other than English spoken at home, pct age 5+, 2008-2012	5.4%	6.6%
High school graduate or higher, percent of persons age 25+, 2008-2012	87.0%	83.9%
Bachelor's degree or higher, percent of persons age 25+, 2008-2012	23.5%	23.5%
Veterans, 2008-2012	13,277	493,980
Mean travel time to work (minutes), workers age 16+, 2008-2012	27.4	24.1
Housing units, 2012	66,765	2,834,620
Homeownership rate, 2008-2012	72.7%	68.4%
Housing units in multi-unit structures, percent, 2008-2012	15.2%	18.2%
Median value of owner-occupied housing units, 2008-2012	\$175,500	\$138,700
Households, 2008-2012	60,529	2,468,841
Persons per household, 2008-2012	2.64	2.51
Per capita money income in past 12 months (2012 dollars), 2008-2012	\$27,823	\$24,294
Median household income, 2008-2012	\$55,560	\$44,140
Persons below poverty level, percent, 2008-2012	9.8%	17.3%

Business QuickFacts	Sumner County	Tennessee
Private nonfarm establishments, 2011	2,833	129,489 ¹
Private nonfarm employment, 2011	36,154	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	0.9%	1.6% ¹
Nonemployer establishments, 2011	13,447	473,451
Total number of firms, 2007	15,402	545,348
Black-owned firms, percent, 2007	3.2%	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	S	0.5%
Asian-owned firms, percent, 2007	S	2.0%
Native Hawaiian and Other Pacific Islander-owned firms, percent, 2007	F	0.1%

Hispanic-owned firms, percent, 2007	1.2%	1.6%
Women-owned firms, percent, 2007	24.2%	25.9%
Manufacturers shipments, 2007 (\$1000)	1,741,400	140,447,760
Merchant wholesaler sales, 2007 (\$1000)	1,634,893	80,116,528
Retail sales, 2007 (\$1000)	1,300,149	77,547,291
Retail sales per capita, 2007	\$8,521	\$12,563
Accommodation and food services sales, 2007 (\$1000)	155,496	10,626,759
Building permits, 2012	592	20,147

Geography QuickFacts	Sumner County	Tennessee
Land area in square miles, 2010	529.45	41,234.90
Persons per square mile, 2010	303.4	153.9
FIPS Code	165	47
Metropolitan or Micropolitan Statistical Area	Nashville- Davidson-- Murfreesboro --Franklin, TN Metro Area	

1: Includes data not distributed by county.

(a) Includes persons reporting only one race.

(b) Hispanics may be of any race, so also are included in applicable race categories.

D: Suppressed to avoid disclosure of confidential information

F: Fewer than 25 firms

FN: Footnote on this item for this area in place of data

NA: Not available

S: Suppressed; does not meet publication standards

X: Not applicable

Z: Value greater than zero but less than half unit of measure shown

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits
Last Revised: Thursday, 27-Mar-2014 09:57:50 EDT

U.S. Department of Commerce

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People Business Geography Data Research Newsroom Search

State & County QuickFacts

Macon County, Tennessee

People QuickFacts	Macon County	Tennessee
Population, 2013 estimate	22,701	6,495,978
Population, 2012 estimate	22,531	6,454,914
Population, 2010 (April 1) estimates base	22,248	6,346,113
Population, percent change, April 1, 2010 to July 1, 2013	2.0%	2.4%
Population, percent change, April 1, 2010 to July 1, 2012	1.3%	1.7%
Population, 2010	22,248	6,346,105
Persons under 5 years, percent, 2012	7.0%	6.3%
Persons under 18 years, percent, 2012	24.9%	23.1%
Persons 65 years and over, percent, 2012	14.9%	14.2%
Female persons, percent, 2012	50.9%	51.2%
White alone, percent, 2012 (a)	97.5%	79.3%
Black or African American alone, percent, 2012 (a)	0.6%	17.0%
American Indian and Alaska Native alone, percent, 2012 (a)	0.7%	0.4%
Asian alone, percent, 2012 (a)	0.3%	1.6%
Native Hawaiian and Other Pacific Islander alone, percent, 2012 (a)	Z	0.1%
Two or More Races, percent, 2012	0.9%	1.6%
Hispanic or Latino, percent, 2012 (b)	4.7%	4.8%
White alone, not Hispanic or Latino, percent, 2012	93.5%	75.1%
Living in same house 1 year & over, percent, 2008-2012	84.9%	84.4%
Foreign born persons, percent, 2008-2012	4.0%	4.5%
Language other than English spoken at home, pct age 5+, 2008-2012	4.2%	6.6%
High school graduate or higher, percent of persons age 25+, 2008-2012	75.1%	83.9%
Bachelor's degree or higher, percent of persons age 25+, 2008-2012	8.5%	23.5%
Veterans, 2008-2012	1,309	493,980
Mean travel time to work (minutes), workers age 16+, 2008-2012	29.8	24.1
Housing units, 2012	9,932	2,834,620
Homeownership rate, 2008-2012	72.8%	68.4%
Housing units in multi-unit structures, percent, 2008-2012	8.9%	18.2%
Median value of owner-occupied housing units, 2008-2012	\$91,800	\$138,700
Households, 2008-2012	8,422	2,468,841
Persons per household, 2008-2012	2.61	2.51
Per capita money income in past 12 months (2012 dollars), 2008-2012	\$17,666	\$24,294
Median household income, 2008-2012	\$35,452	\$44,140
Persons below poverty level, percent, 2008-2012	23.5%	17.3%

Business QuickFacts	Macon County	Tennessee
Private nonfarm establishments, 2011	328	129,489 ¹
Private nonfarm employment, 2011	3,297	2,300,542 ¹
Private nonfarm employment, percent change, 2010-2011	0.5%	1.6% ¹
Nonemployer establishments, 2011	1,655	473,451
Total number of firms, 2007	S	545,348
Black-owned firms, percent, 2007	S	8.4%
American Indian- and Alaska Native-owned firms, percent, 2007	S	0.5%
Asian-owned firms, percent, 2007	S	2.0%
Native Hawaiian and Other Pacific Islander-owned firms, percent, 2007	S	0.1%

Hispanic-owned firms, percent, 2007	S	1.6%
Women-owned firms, percent, 2007	S	25.9%
Manufacturers shipments, 2007 (\$1000)	D	140,447,760
Merchant wholesaler sales, 2007 (\$1000)	30,350	80,116,528
Retail sales, 2007 (\$1000)	167,327	77,547,291
Retail sales per capita, 2007	\$7,713	\$12,563
Accommodation and food services sales, 2007 (\$1000)	11,896	10,626,759
Building permits, 2012	15	20,147

	Macon County	Tennessee
Geography QuickFacts		
Land area in square miles, 2010	307.14	41,234.90
Persons per square mile, 2010	72.4	153.9
FIPS Code	111	47
Metropolitan or Micropolitan Statistical Area	Nashville- Davidson- Murfreesboro --Franklin, TN Metro Area	

1: Includes data not distributed by county.

(a) Includes persons reporting only one race.

(b) Hispanics may be of any race, so also are included in applicable race categories.

D: Suppressed to avoid disclosure of confidential information

F: Fewer than 25 firms

FN: Footnote on this item for this area in place of data

NA: Not available

S: Suppressed; does not meet publication standards

X: Not applicable

Z: Value greater than zero but less than half unit of measure shown

Source U.S. Census Bureau: State and County QuickFacts. Data derived from Population Estimates, American Community Survey, Census of Population and Housing, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits
Last Revised: Thursday, 27-Mar-2014 09:57:48 EDT

Attachment C, Economic Feasibility – 1

Architect Letter



HINSON
MILLER
KICKIRILLO
ARCHITECTS PLLC

August 15, 2014

Ms. Melanie Hill
Executive Director
State of Tennessee
Health Services and Development Agency
500 Deadrick Street, Suite 850
Nashville, TN 37243

RE: Sumner Regional Medical Center-Sumner Station Facility
PET Scanner – Verification of Construction Cost

Dear Ms. Hill:

We have reviewed the construction cost developed for a PET scanner proposed for SRMC's outpatient Imaging Center at the Sumner Station facility. The construction cost of \$460,000.00 is based on 1,425 square feet of interior renovation for the scan room and its support spaces.

It is our professional opinion that the construction cost proposed which equates to \$322.80 per square foot is consistent with historical data based on our experience with similar type projects. It is important to note, that our opinion is based on normal market conditions, price escalation, etc.

The project will be developed under the current codes and standards enforced by the State of Tennessee as follows:

2012 International Building Code/2012 International Mechanical Code/2012 International Plumbing Code
2012 International Gas Code
2005 National Electrical Code
2012 NFPA 1, excluding NFPA 5000
2012 NFPA 101, Life Safety Code
2010 FGI Guidelines for the Design and Construction of Health Care Facilities
2002 North Carolina Accessibility Code with 2004 Amendments/2010 Americans with Disabilities Act (ADA)

Sincerely,

HINSON MILLER KICKIRILLO ARCHITECTS PLLC

Donald C. Miller, NCARB, AIA – [TN License No. 100019]

Description of construction/renovation of space:

Sumner Regional Medical Center has proposed to add a PET scanner to their existing outpatient Imaging Center at the Sumner Station facility in Gallatin, TN. The project includes approximately 1,425 square feet of interior renovation that will include the PET scan room, control room, prep/staging spaces, patient toilet and a hot lab.

The construction will include demolition and alterations to existing walls, metal stud framing, architectural woodwork, steel doors/frames, wood doors, drywall, interior finishes, radiation protection, mechanical, plumbing, electrical and fire protection systems.

Describe patient access to the proposed location, including public transportation options, if applicable:

Patient access is provided off of Big Station Camp Boulevard. There is a covered entrance at grade level on the North side of the Sumner Station facility that serves the current outpatient Imaging Center suite. Parking for patients is provided directly adjacent this entrance, including handicapped accessible spaces.

Nashville Metropolitan Transit Authority (MTA) serves Gallatin, but not direct service to the Sumner Station facility. Mid-Cumberland Human Resources Agency RTS Public Transit and taxi services are services that can provide public transportation to this facility.

Attachment C, Economic Feasibility - 2

Funding Letter

LIFEPOINT HOSPITALS®

September 9, 2014

Melanie Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson, 9th Floor
502 Deaderick Street
Nashville, TN 37243

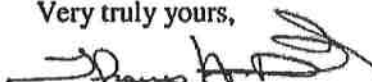
Re: Sumner Regional Medical Center – Certificate of Need for Positron Emission
Tomography (PET-CT)

Dear Ms. Hill:

I am the Chief Financial Officer of LifePoint Hospitals ("LifePoint"), the parent organization of Sumner Regional Medical Center ("SRMC"). This letter confirms that LifePoint has sufficient resources to fund the cost of approximately \$2,687,896 for SMRC's project to PET-CT services at its Sumner Station Campus. LifePoint is committed to make these funds available to SMRC.

Thank you for your attention to this matter.

Very truly yours,



330 Seven Springs Way, Brentwood, Tennessee 37027

Phone 615.920.7000

LIFEPOINTHOSPITALS.COM

Attachment C, Economic Feasibility - 9

Financial Statement



INCOME STATEMENT

16750 - SUMNER REGIONAL MEDICAL CENTER

LPNT GROUP OPERATIONS
EASTERN GROUP
HIGHTPOINT MARKET

CURRENT MONTH				MED/SURG				YEAR-TO-DATE				
ACTUAL	BUDGET	\$Dollar	PCT%	December 2013	ACTUAL	BUDGET	\$Dollar	PCT%	LAST YEAR	\$Dollar	PCT%	
Revenues												
2,829,850	3,372,581	(542,731)	-16.09%	3,105,617	(275,767)			-8.88%	ROUTINE REVENUE	37,564,617	(1,073,449)	-2.86%
18,427,906	16,340,537	2,087,369	12.77%	15,611,025	2,816,881			18.04%	IP ANCILLARY	184,366,628	16,667,501	9.04%
21,257,756	19,713,118	1,544,638	7.84%	20,117,642	2,541,114			13.59%	GROSS IP REV	15,594,052	15,997,945	26.06%
21,380,922	21,766,928	(386,006)	-1.77%	18,177,736	1,263,186			6.28%	OP ANCILLARY	257,890,088	228,705,917	9.95%
42,638,678	41,480,046	1,158,632	2.79%	38,934,378	3,804,300			9.80%	TOTAL PAT REV	497,868,807	18,047,474	3.76%
77,191	185,043	(107,852)	-58.28%	150,081	(72,890)			-48.57%	OTHER OPER INCOME	2,220,516	(1,165,783)	-52.50%
42,715,869	41,665,089	1,050,780	2.52%	38,984,459	3,731,410			9.57%	GROSS REVENUE	16,881,691	419,278,555	3.50%
Deductions												
8,496,527	11,160,913	(2,664,386)	-23.87%	10,552,007	(2,055,480)			-19.48%	MEDICARE CURRENT YR	127,984,513	(4,247,411)	-3.32%
(184,146)	(344,154)	160,008	46.49%	(284,229)	100,083			-35.21%	MEDICAID CURRENT YR	(4,181,061)	432,345	-10.34%
219,151	142,488	76,663	53.80%	99,200	119,951			120.92%	CHAMPUS CONTRACTUALS	1,690,936	273,159	16.15%
0	0	0	0.00%	0	0			0.00%	PR YR CONTRACTUALS	264,792	0	0.00%
18,220,310	16,998,216	1,222,094	7.19%	15,243,724	2,976,586			19.53%	HMO/PRO DISNTS INC MIEMA	197,188,453	12,307,504	6.24%
MGD												
437,639	889,733	(452,094)	-50.81%	600,697	(163,058)			-27.14%	CHARITY DISCOUNTS	10,121,287	(884,564)	-8.74%
3,859,313	1,277,517	2,581,796	202.09%	1,508,286	2,351,027			155.87%	OTHER DEDUCTIONS	4,638,950	4,638,950	31.37%
2,107,248	1,890,675	216,573	11.45%	1,856,843	250,405			13.49%	BAD DEBT	21,870,425	2,667,576	12.20%
33,156,042	32,015,388	1,140,654	3.56%	29,576,528	3,579,514			12.10%	TOTAL DEDUCTIONS	369,460,550	15,452,351	4.18%
9,559,827	9,648,701	(89,874)	-0.93%	9,407,931	151,896			1.61%	TOTAL NET REV	112,581,299	1,429,340	1.27%
Operating Expenses												
3,461,267	3,473,375	(12,108)	-0.35%	3,312,226	149,041			4.50%	SALARIES	37,885,283	2,169,872	5.73%
8,859	16,149	(7,290)	-45.14%	9,042	(183)			-2.02%	CONTRACT LABOR	192,832	233,407	121.04%
641,324	780,382	(139,058)	-17.82%	500,848	140,476			28.05%	EMPLOYEE BENEFITS	9,018,393	(802,934)	-8.90%
1,458,447	1,638,049	(179,602)	-10.96%	1,298,252	159,195			12.25%	SUPPLIES	18,976,525	(1,860,351)	-9.80%
300,199	215,245	84,954	39.47%	237,764	62,435			28.25%	PROFESSIONAL FEES	2,519,940	951,689	37.77%
337,850	570,198	(232,348)	-40.75%	482,503	(144,653)			-29.98%	CONTRACT SERVICES	5,317,210	(26,008)	-0.49%
315,407	300,117	15,290	5.09%	290,265	25,142			8.66%	REPAIRS & MAINTENANCE	3,565,229	288,209	8.08%
(1,922,248)	(1,053)	(1,921,195)	182449.67%	13,057	(1,935,305)			-14821.97%	RENTS & LEASES	(11,847)	(1,213,275)	10241.20%
Capital and Other Costs												
216,320	218,216	(1,896)	-0.87%	216,480	(160)			-0.07%	UTILITIES	2,591,216	74,158	2.86%
39,739	63,074	(23,335)	-37.00%	5,809	33,930			584.09%	INSURANCE	(148,955)	(842,292)	-19.80%
0	0	0	0.00%	0	0			0.00%	INVESTMENT INCOME	0	0	0.00%
507,624	491,984	15,640	3.18%	469,535	38,089			8.11%	NON INCOME TAXES	5,915,888	44,603	0.75%
298,430	305,506	(7,076)	-2.32%	241,241	57,189			23.71%	OTHER OPER EXPENSE	2,797,927	(438,271)	-15.66%
5,663,218	8,071,242	(2,408,024)	-29.83%	7,078,022	(1,414,804)			-19.99%	TOTAL OPER EXP	89,521,049	(727,856)	-0.81%
3,896,609	1,578,459	2,318,150	146.86%	2,329,909	1,566,700			67.24%	EBDITA	23,060,250	2,157,196	9.35%
Capital and Other Costs												
664,830	599,976	64,854	10.81%	762,907	(98,077)			-12.86%	DEPRECIATION	8,003,474	404,687	5.06%
0	0	0	0.00%	0	0			0.00%	AMORTIZATION	0	0	0.00%
0	0	0	0.00%	0	0			0.00%	OTHER NON OPER EXP	0	0	0.00%
126,417	148,941	(22,524)	-15.12%	152,808	(26,391)			-17.27%	INTEREST	1,843,738	(89,014)	-4.83%
367,295	367,295	0	0.00%	340,830	26,465			7.76%	MANAGEMENT FEES	4,407,540	0	0.00%
0	0	0	0.00%	0	0			0.00%	MINORITY INTEREST	0	0	0.00%
1,158,542	1,116,212	42,330	3.79%	1,258,545	(98,003)			-7.80%	TOT CAPITAL/OTHER	14,254,752	315,673	2.21%
2,738,067	462,247	2,275,820	492.34%	1,073,364	1,664,703			155.09%	PRE TAX INCOME	8,805,498	1,841,523	20.91%
Taxes on Income												
0	0	0	0.00%	0	0			0.00%	FED INCOME TAXES	0	0	0.00%
0	0	0	0.00%	0	0			0.00%	STATE INCOME TAXES	0	0	0.00%
0	0	0	0.00%	0	0			0.00%	TOTAL TAXES INCOME	0	0	0.00%
2,738,067	462,247	2,275,820	492.34%	1,073,364	1,664,703			155.09%	NET INCOME	8,805,488	1,841,523	20.91%
										6,701,659	3,945,362	169.86%



BALANCE SHEET

LPNT GROUP OPERATIONS
EASTERN GROUP
HIGHTPOINT MARKET

BEGIN	CHANGE	ENDING
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December 2013
Balance Sheet

BEGIN	CHANGE	ENDING
-------	--------	--------

Current Assets

CASH & CASH EQUIVALENTS	-803,262	-193,037	-996,299	503,111	-1,499,410	-996,299
MARKETABLE SECURITIES	0	0	0	0	0	0
Patient Accounts Receivables						
PATIENT RECEIVABLES	37,091,582	-557,355	36,534,227	30,754,157	5,780,070	36,534,227
LESS ALLOW FOR GOVT RECEIVABLE	0	0	0	0	0	0
LESS ALLOWS - BAD DEBT	-18,350,139	683,086	-17,667,053	-14,585,007	-3,082,046	-17,667,053
NET PATIENT RECEIVABLES	18,741,443	125,731	18,867,174	16,169,150	2,698,024	18,867,174
Final Settlements						
DUE TO/FROM GOVT PROGRAMS	-586,317	0	-586,317	-618,647	32,330	-586,317
ALLOWES DUE GOVT PROGRAMS	-38,444	0	-38,444	-36,652	-1,792	-38,444
NET FINAL SETTLEMENTS	-624,761	0	-624,761	-655,299	30,538	-624,761
NET ACCOUNTS RECEIVABLE						
INVENTORIES	18,116,682	125,731	18,242,413	15,513,851	2,728,562	18,242,413
PREPAID EXPENSES	3,045,632	14,406	3,060,038	3,043,772	16,266	3,060,038
OTHER RECEIVABLES	659,320	1,182,270	1,841,590	397,631	1,443,959	1,841,590
TOTAL CURRENT ASSETS	358,168	-14,955	343,213	78,582	264,631	343,213
Property, Plant, Equipment						
LAND	21,376,540	1,114,415	22,490,955	19,536,947	2,954,008	22,490,955
BLDGS AND IMPROVEMENT	4,170,000	2,702,700	6,872,700	4,170,000	2,702,700	6,872,700
EQUIPMENT OWNED	99,024,614	15,365,552	114,390,166	99,024,614	15,365,552	114,390,166
EQUIPMENT CAPITAL LEASES	27,511,301	350,572	27,861,873	28,467,849	-605,976	27,861,873
CONSTRUCTION IN PROGRESS	0	0	0	0	0	0
GROSS PP&E	36,595	34,888	71,483	6,111	65,372	71,483
LESS ACCUMULATED DEPRECIATION	130,742,510	18,453,712	149,196,222	131,668,574	17,527,648	149,196,222
NET PP&E	-27,135,264	-652,739	-27,788,003	-21,054,579	-6,733,424	-27,788,003
Other Assets						
INVESTMENTS	103,607,246	17,800,973	121,408,219	110,613,995	10,794,224	121,408,219
NOTES RECEIVABLES	0	0	0	0	0	0
INTANGIBLE ASSETS - NET	0	0	0	0	0	0
INVESTMENT IN SUBSIDIARIES	26,417,431	-53,712	26,363,719	26,015,572	348,147	26,363,719
OTHER ASSETS	0	0	0	0	0	0
TOTAL OTHER ASSETS	65,413	-65,313	100	65,413	-65,313	100
GRAND TOTAL ASSETS	26,482,844	-119,025	26,363,819	26,080,985	282,834	26,363,819
	151,466,630	18,796,363	170,262,993	156,231,927	14,031,066	170,262,993



BALANCE SHEET **16750 - SUMNER REGIONAL MEDICAL CENTER**

LPNT GROUP OPERATIONS
 EASTERN GROUP
 HIGHTPOINT MARKET

CURRENT MONTH		December 2013	
BEGIN	CHANGE	BEGIN	ENDING
Liabilities & Equity			
Current Liabilities			
3,058,995	-536,652	2,522,343	2,522,343
2,493,424	359,005	2,852,429	2,852,429
1,111,487	608,199	1,720,686	1,720,686
0	0	0	0
0	0	0	0
318,800	10,825	329,625	329,625
873,872	-315,830	558,042	558,042
0	0	0	0
7,856,578	126,547	7,983,125	7,983,125
Long Term Debt			
3,703,996	-31,521	3,672,475	3,672,475
121,897,188	18,113,315	140,010,503	140,010,503
0	0	0	0
125,601,184	18,081,794	143,682,978	143,682,978
Deferred Credits and Other Liabilities			
0	0	0	0
0	0	0	0
2,172,172	-2,150,045	22,127	22,127
2,172,172	-2,150,045	22,127	22,127
Equity			
0	0	0	0
0	0	0	0
7,927,742	0	7,927,742	7,927,742
7,908,954	2,738,067	10,647,021	10,647,021
0	0	0	0
0	0	0	0
15,836,696	2,738,067	18,574,763	18,574,763
151,466,630	18,796,363	170,262,993	170,262,993

**Attachment C, Contribution to the
Orderly Development of Health Care - 1**

Managed Care Contracts and Transfer Agreements

HighPoint Health System Affiliates

Insurance Contract Name and Network Plan Types

Last Updated 1-2014

Insurance Contract Name and Network Plan Types	Summer Regional Medical Center		Trousdale Medical Center	Riverview Regional Medical Center	Summer Homecare and Hospice			
	Hospital	Summer Inpatient Rehab Unit	Hospital	Hospital	Carthage	Gallatin	Goodlettsville	Hospice
AmeriChoice - (United Healthcare Community Plan as of 01/01/11)	●		◆ No Swing	* No Swing	■	■	■	■
AmeriGroup - Community Care	●		◆ No Swing	* No Swing	■	■	■	■
Aetna	●	●	◆	◆	■	■	■	■
BeechStreet	●	●	◆	◆	■	■	■	■
Blue Network P (Blue Preferred)	●	●	◆ No Swing	* No Swing	■	■	■	■
Blue Network S (Blue Select)	●	●	◆ No Swing	* No Swing	■	■	■	■
Blue Network V (CoverTN)	● No Wound Care	●	◆ No Swing	* No Swing	■	■	■	■
BlueCare / TennCare Select	●		◆ No Swing	* No Swing	■	■	■	■
Center Care PPO	●	●	◆	◆	■	■	■	■
Cigna	●	●	◆	◆	■	■	■	■
Corvel Work Comp	●	●	◆	◆	■	■	■	■
First Health (Includes CCN PPO)	●	●	◆	◆	■	■	■	■
Great West Healthcare	●	●	◆	◆	■	■	■	■
HealthScope Benefits (Access the CenterCare Network in TN)	●	●	◆	◆	■	■	■	■
HealthSpring Commercial Plans	●	●	◆	◆	■	■	■	■
HealthSpring Medicare Advantage Plans	●	●	◆	◆	■	■	■	■
Humana ChoiceCare Network	●	●	◆	◆	■	■	■	■
Humana Medicare PPO	●	●	◆	◆	■	■	■	■
MultiPlan	●	●	◆	◆	■	■	■	■
NovaNet	●	●	◆	◆	■	■	■	■
PPO USA (GEHA)	●	●	◆	◆	■	■	■	■
ppoNext	●	●	◆	◆	■	■	■	■
Prime Health Services	●	●	◆	◆	■	■	■	■
Private Health Care Systems (PHCS)	●	●	◆	◆	■	■	■	■
Principal Edge Network	●	●	◆	◆	■	■	■	■
Provider Networks of America (ProNet access Signature PPO in TN)	●	●	◆	◆	■	■	■	■
Signature Health Alliance	●	●	◆	◆	■	■	■	■
Synergy Health Network	●	●	◆	◆	■	■	■	■
TriCare Military Services (Humana Prime Plan)	●	●	◆	◆	■	■	■	■
United HealthCare	●	●	◆	◆	■	■	■	■
USA Health Network (USA MCO)	●	●	◆	◆	■	■	■	■
Windsor	●	●	◆	◆	■	■	■	■
Windsor - Geopsychn	●	●	◆	◆	■	■	■	■
Medicare Advantage Plans PFFS-Do Not Require Contracts or Networks all facilities can treat these patients.	●	●	◆	◆	■	■	■	■
Private Fee For Service	●	●	◆	◆	■	■	■	■



My Custom Report

Contract Number	Contract Type	Contracting Entity	Department	Effective Date	Expiration Date	Responsible Party, Primary	Vendor Other Party
<u>6588.12267C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	3/16/1999	03/15/2015	Melton, Anne	Hendersonville Nursing Home, LTD.
<u>6588.12270C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	3/29/2010	03/28/2015	Melton, Anne	RAI Care Centers of Gallatin I, LLC
<u>6588.12272C</u>	Transfer Agreements	Medical Center, LLC	Cardiology	7/30/2009	07/31/2016	Melton, Anne	Centennial Medical Center
<u>6588.12274C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	12/20/1993	12/19/2014	Melton, Anne	NHC of Hendersonville
<u>6588.12282C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	1/9/1995	01/08/2015	Melton, Anne	Royal Care of Westmoreland
<u>6588.12285C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	6/1/2007	05/31/2015	Melton, Anne	Golden Living
<u>6588.12288C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	12/20/1993	12/19/2014	Melton, Anne	Hartsville Convalescent Center
<u>6588.12298C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	1/30/1998	01/29/2015	Melton, Anne	LifeTrust America, Inc.
<u>6588.12303C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	9/1/1999	08/31/2014	Melton, Anne	Madison Healthcare and Rehabilitation Center
<u>6588.12310C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	9/27/1994	09/26/2014	Melton, Anne	Middle Tennessee Rehab at Sumner
<u>6588.12313C</u>	Transfer Agreements	Medical Center, LLC	Administration	12/20/1993	12/19/2014	Melton, Anne	Gallatin Health Care Associates
<u>6588.12315C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	9/1/2006	08/31/2014	Melton, Anne	Patient Partners Surgery Center
<u>6588.12316C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	11/21/1993	11/20/2014	Melton, Anne	Highland Manor
<u>6588.12328C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	2/1/2000	01/31/2015	Melton, Anne	Vanderbilt Children's Hospital
<u>6588.12331C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	10/18/1999	06/25/2015	Melton, Anne	Summit Medical Center
<u>6588.12334C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	5/1/2011	04/30/2015	Melton, Anne	Saint Thomas Hospital
<u>6588.12370C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	11/7/2011	11/06/2014	Melton, Anne	Riverview Regional Medical Center South
<u>6588.12378C</u>	Transfer Agreements	Sumner Regional Medical Center, LLC	Administration	10/26/1999	10/25/2014	Melton, Anne	Green Surgery Center, LLC
						No. Of Contract:	18

98

**Attachment C, Contribution to the Orderly Development of
Health Care – 2**

Letter of Support

TENNESSEE ONCOLOGY

www.tnoncology.com

MEDICAL ONCOLOGY/
HEMATOLOGY

Dianna L. Shipley, M.D.

Mathew J. Joseph, M.D.

Amy Cox, APRN-BC, AOCNP

Cyndi M. Adair, ACNP-BC

Ms. Melanie Hill
Executive Director
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Sumner Regional Medical Center – Certificate of Need
Application to Initiate PET Service

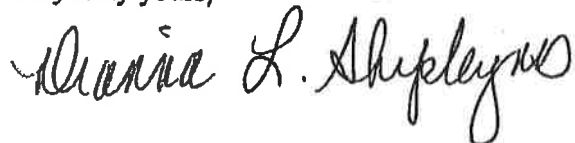
Dear Ms. Hill:

We are submitting this letter regarding the proposal by Sumner Regional Medical Center to initiate PET service at its Sumner Station Campus.

Tennessee Oncology is composed of 75 medical oncologists and hematologists, with over 30 practice locations throughout Middle Tennessee, Chattanooga, and Northwest Georgia. We serve more cancer patients in Middle Tennessee than any other oncology group. One of our locations in Middle Tennessee is our clinic in Gallatin in close proximity to Sumner Regional Medical Center.

PET is a critically important service for cancer diagnosis and treatment planning. We support the decision by Sumner Regional to initiate PET services at its Sumner Station Campus. PET services are not currently available in the community, and patients from this area are required to travel to Nashville to have PET scans. The availability of PET service at Sumner Station will reduce the travel burdens on cancer patients, many of whom are elderly. We urge the Agency to approve the request by Sumner Regional.

Very truly yours,



**Attachment C, Contribution to the
Orderly Development of Health Care – 7(c)**

License and Joint Commission Documentation

Board for Licensing Health Care Facilities



State of Tennessee

DEPARTMENT OF HEALTH

No. of Beds 0155
0000000116

This is to certify, that a license is hereby granted by the State Department of Health to

SUMNER REGIONAL MEDICAL CENTER, LLC *to conduct and maintain a*

Hospital SUMNER REGIONAL MEDICAL CENTER

Located at 555 HARTSVILLE PIKE, GALLATIN

County of SUMNER, Tennessee.

This license shall expire JUNE 25, 2015, *and is subject*

to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable, and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the State Department of Health issued thereunder.

In Witness Whereof, we have hereunto set our hand and seal of the State this 25TH *day of* JUNE, 2014.

In the Distinct Category(ies) of: GENERAL HOSPITAL
PEDIATRIC GENERAL HOSPITAL



By Theresa J. Davis, MPH
DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

By Mark J. Dyer
COMMISSIONER

Sumner Regional Medical Center

Gallatin, TN

has been Accredited by



The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the
Hospital Accreditation Program

September 15, 2012

Accreditation is customarily valid for up to 36 months.

Isabel V. Hoverman, MD, MACP
Chair, Board of Commissioners

Organization ID #: 7832
Print/Reprint Date: 01/08/13

Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit, national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.



This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission. Please consult Quality Check on The Joint Commission's website to confirm the organization's current accreditation status and for a listing of the organization's locations of care.

Standard	Standard Text	Total EPs	Addressed 45 Day EPs	Chapter Owner
MM.04.01.01	Medication orders are clear and accurate.	1	0	
NPSG.03.04.01	Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. Note: Medication containers include syringes, medicine cups, and basins.	1	0	Tommy Cothron
UP.01.03.01	A time-out is performed before the procedure.	1	0	Becky Grant
ESC 60 Day				Becky Grant
Standard	Standard Text	Total EPs	Addressed 60 Day EPs	Chapter Owner
EC.02.05.09	The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.	1	0	
LS.02.01.20	The hospital maintains the integrity of the means of egress.	1	0	Mike Messer
LS.02.01.35	The hospital provides and maintains systems for extinguishing fires.	1	0	Mike Messer
MM.03.01.01	The hospital safely stores medications.	1	0	Tommy Cothron
MS.08.01.03	Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to revoke an existing privilege prior to or at the time of renewal.	1	0	
PC.01.02.03	The hospital assesses and reassesses the patient and his or her condition according to defined time frames.	1	0	Stacey Crudup/Tammy Carter
PC.01.03.01	The hospital plans the patient's care.	1	0	Anne Melton/Penny Clark
PC.03.05.03	For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital uses restraint or seclusion safely.	1	0	Anne Melton/Penny Clark
RC.01.01.01	The hospital maintains complete and accurate medical records for each individual patient.	1	0	Anne Melton/Penny Clark
RC.02.03.07	Qualified staff receive and record verbal orders.	1	0	Jon Koederitz

Sumner Regional Medical Center
Organization ID: 7832
555 Hartsville Pike Gallatin, TN 37066

Accreditation Activity - Measure of Success Form
Due Date: 4/4/2013

HAP Standard MM.04.01.01 Medication orders are clear and accurate.

Elements of Performance:

13. The hospital implements its policies for medication orders.

Scoring C
Category:

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual
Goal (%): 94

Month 2 Date: 12/2012

Month 2 Actual
Goal (%): 95

Month 3 Date: 01/2013

Month 3 Actual
Goal (%): 98

Month 4 Date: 02/2013

Month 4 Actual
Goal (%): 97

Actual Average
Goal (%): 96

Optional
Comments:

HAP Standard PC.01.02.03 The hospital assesses and reassesses the patient and his or her condition according to defined time frames.

Elements of Performance:

5. For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a

procedure requiring anesthesia services. (See also MS.03.01.01, EP 8; RC.02.01.03, EP 3)

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 97

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 98

Month 3 Date: 01/2013

Month 3 Actual Goal (%): 94

Month 4 Date: 02/2013

Month 4 Actual Goal (%): 94

Actual Average Goal (%): 96

Optional Comments:

HAP	Standard PC.03.05.03	For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital uses restraint or seclusion safely.
------------	-----------------------------	---

Elements of Performance:

2. For hospitals that use Joint Commission accreditation for deemed status purposes: The use of restraint and seclusion is in accordance with a written modification to the patient's plan of care.

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 84

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 100

Month 3 Date: 01/2013

Month 3 Actual Goal (%): 100

Month 4 Date: 02/2013

Month 4 Actual Goal (%): 100

Actual Average Goal (%): 96

Optional Comments:

HAP	Standard UP.01.03.01	A time-out is performed before the procedure.
------------	-----------------------------	--

Elements of Performance:

5. Document the completion of the time-out. Note: The hospital determines the amount and type of

SEP 15 14 42:26

documentation.

Scoring Category: C

Stated Goal (%): 90

Month 1 Date: 11/2012

Month 1 Actual Goal (%): 95

Month 2 Date: 12/2012

Month 2 Actual Goal (%): 98

Month 3 Date: 01/2012

Month 3 Actual Goal (%): 99

Month 4 Date: 2/2012

Month 4 Actual Goal (%): 98

Actual Average Goal (%): 97

Optional Comments:

**Attachment C, Contribution to the
Orderly Development of Health Care – 7(d)**

Survey and POC



RECEIVED

OCT 18 2006

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
BUREAU OF HEALTH LICENSURE AND REGULATION
MIDDLE TENNESSEE REGIONAL OFFICE
710 HART LANE, 1ST FLOOR
NASHVILLE, TENNESSEE 37247-0530
PHONE (615) 650-7100
FAX (615) 650-7101

October 17, 2006

R. Bruce James, Administrator
Sumner Regional Medical Center
555 Hartsville Pike
Gallatin, TN 37066

Dear Mr. James:

Enclosed is the statement of deficiencies developed as a result of the state licensure survey completed on October 11, 2006 at Sumner Regional Medical Center.

Please provide us with documentation to describe how and when these deficiencies will be corrected. This information should be received in our office within ten (10) calendar days after receipt of this letter. We are requesting that you assure correction of the cited deficiencies no later than sixty (60) days from the date of the survey. A follow-up visit may be conducted, if your allegation of correction is reasonable and convincing. Failure to provide an acceptable plan of correction could result in a referral to the Board of Licensing Health Care Facilities for whatever action they deem appropriate.

In order for your Plan of Correction (PoC) to be acceptable, it should address the following:

1. How you will correct the deficiency;
2. Who will be responsible for correcting the deficiency;
3. The date the deficiency will be corrected; and
4. How you will prevent the same deficiency from happening again.

Should you have any questions, or if there is any way this office may be of assistance, please do not hesitate to call.

Sincerely,

A handwritten signature in cursive script that reads "Nina Monroe".

Nina Monroe, Regional Administrator
Middle Tennessee Regional Office

Enclosure
NM/dv

PRINTED: 10/16/2006
FORM APPROVED

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 404	<p>1200-8-1-.04 (4) Administration</p> <p>(4) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A hospital which violates a required policy also violates the rule and regulation establishing the requirement.</p> <p>This Statute is not met as evidenced by: Based on observation interview and record review it was determined the facility failed to adhere to the provisions of the facility's policies labeled "Intravascular Devices" and "Medication Administration".</p> <p>The findings included:</p> <p>Observation of one random patient in the facilities Intensive Care Unit on 10/11/06 at 10:40 AM in room 6 revealed a Patient whom had two Intravenous Dressings. One dressing was covering a Triple Lumen Catheter that was located on the Patients right subclavian area of the anterior chest and the other Intravenous access was located in the patients right arm antecubital area. Observation of the dressings revealed there was no documentation on the transparent dressings of either site.</p> <p>Record review Patient #27 of 37 sampled Patients revealed documentation by the Medical Doctor on 10/10/06 at 1500 in the Physicians Progress notes indicating the Triple Lumen Catheter was placed in Patient #27 on 10/10/06. Confirmation was made with the Intensive Care Unit, Care Coordinator of these findings on 10/11/06 at 10:50 AM. The policy labeled</p>	H 404			

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

STATE FORM

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If continuation sheet 1 of 1

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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H 404	<p>Continued From page 1</p> <p>"Intravascular Devices" reads on page 2 of the policy "I. Documentation 1. Record date and time of catheter insertion on label provided in the IV start kit and attach to IV dressing."</p> <p>Tour of the facilities operating room on 10/10/06 at 11:00 AM in room 1 revealed 22 milliliters of a white liquid in a 30 milliliter syringe located on top of an anesthesia cart unattended. Further observation revealed the cart was unlocked. There was no label noted on the syringe containing the 22 milliliters of the white liquid. Interview with an anesthesiologist in the surgery hallway on 10/10/06 at 11:05 reports "We don't label the propofol." Confirmation was made with the Surgery Director on 10/10/06 at 11:06 AM that the medication should be labeled.</p> <p>Review of the facilities policy labeled "Medication Administration" reads under the section labeled Procedure: "12. Medications and solutions both on and off the sterile field should be labeled even if there is only one medication being used. 13. Labeling occurs when any medication or solution is transferred from the original packaging to another. 14. Labels should include drug name, strength, amount, if not used within 24 hours, and expiration time when expiration occurs in less than 24 hours."</p> <p>Observation on 10/10/06 at 3:15 PM during an interview with Patient # 37 of the 37 sampled Patients revealed a right Port-A-Cath central line intravenous dressing with no date and signature. The findings were confirmed in an interview with the 4th Floor charge nurse at this time. Medical record review on 10/10/06 at 3:20 PM revealed a needle and dressing change documented in the</p>	H 404			

Division of Health Care Facilities
STATE FORM

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If continuation sheet 2 of 12

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 404	Continued From page 2 nursing notes at 8:45 AM on 10/10/06. The facility policy to date and initial all intravenous dressings was confirmed on 10/10/06 at 3:20 PM by the Director of Medical/Surgical and the 4th Floor charge nurse. Review of the facility policy entitled, "Intravascular Devices" revealed that documentation should include recording the date and time of the catheter insertion on the label provided in the intravenous start kit and attach to the intravenous dressing.	H 404			
H 647	1200-8-1-.06 (3)(i)4. Basic Hospital Functions (3) Infection Control. (i) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including: 4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies; This Statute is not met as evidenced by: Based on observation and interview it was determined the facility failed to ensure the sterility and package integrity of several random items found in the facilities clinical areas that were out of date as per the manufacturer guidelines. The findings included:	H 647			

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H 647	<p>Continued From page 3</p> <p>During tour in the Intensive Care Unit 10/11/06 at 10:55 AM in the "Line Cart" located in front of the Intensive Care Units Nursing Station revealed a package in the third drawer in the cart that contained a package labeled "Scrub Care Preoperative Skin Care Prep Tray" that had an expiration date printed on the package of June 2006. Confirmation was made with the Intensive Care Unit/ Care Coordinator at 11:00 AM that the package was out of date.</p> <p>Observation during a tour of the newborn nursery on 10/11/06 at 12:30 PM revealed expired supply items in the third drawer of the emergency supply cabinet.</p> <p>One 18 gauge Insyte Autoguard chest tube needle with an expiration date of January 2004. Three 14 gauge Insyte Autoguard chest tube needles with an expiration date of March 2005. Three 16 gauge Insyte Autoguard chest tube needles with an expiration date of January 2006.</p> <p>The above findings were confirmed with the Director of Women's Services and the Accreditation Coordinator on 10/11/06 at 1:00 PM.</p> <p>Review of the facility policy entitled, "Shelf Life of Sterile Supplies" revealed that all expiration dated packages of purchased sterile supplies must be checked and rotated weekly.</p>	H 647			
H 665	<p>1200-8-1-.06 (3)(o) Basic Hospital Functions</p> <p>(3) Infection Control.</p> <p>(o) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.</p>	H 665			

Division of Health Care Facilities
STATE FORM

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If continuation sheet 4 of 12

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H 665	<p>Continued From page 4</p> <p>This Statute is not met as evidenced by: Based on observation and interview, it was determined that the facility failed to provide a clean and sanitary physical environment</p> <p>The findings included:</p> <p>Observation on 10/10/06 at 11:10 AM during a tour of the 4th Floor (West) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator at this time.</p> <p>Observation on 10/10/06 at 2:40 PM during a tour of the 4th Floor (East) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator at this time. Continued tour of this unit at 2:45 PM revealed an empty patient room with an overbed table with dried brown and white matter on the internal compartment. The findings were confirmed with the accreditation coordinator at this time. Continued interview with the accreditation coordinator at this time also revealed that the room was cleaned and available for patient occupancy at the time of the observations.</p> <p>Observation on 10/11/06 at 10:00 AM during a tour of the 2nd Floor (West) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator and the director of the 2nd floor at this time.</p> <p>Observation on 10/11/06 at 10:10 AM during a tour of the 2nd Floor (East) kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the</p>	H 665			

Division of Health Care Facilities

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If continuation sheet 5 of 12

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X6) COMPLETE DATE
H 665	Continued From page 5 patient care coordinator and the director of the 2nd floor at this time. Observation on 10/11/06 at 11:50 AM during a tour of the Labor and Delivery unit kitchen revealed a microwave with dried food matter on the inside of the unit. The findings were confirmed with the patient care coordinator and the accreditation coordinator at this time. Continued observation at 11:58 AM revealed a sink in the workroom between the Labor, Delivery, and Recovery room (LDR) #1 and LDR #2 that contained a white container one-half full with a light yellow liquid. The findings were confirmed with the director of women's services at this time and that the container should have been removed after cleaning the room.	H 665		
H 706	1200-8-1-.06 (6)(a) Basic Hospital Functions (6) Pharmaceutical Services. (a) The hospital must have pharmaceutical services that meet the needs of the patients and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. This Statute is not met as evidenced by: Based on observation, interview, and policy review the facility failed to provide Pharmaceutical Services in compliance with approved policies and procedures. The findings included:	H 706		

Division of Health Care Facilities

STATE FORM

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If continuation sheet 6 of 12

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Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/11/2006
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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H 706	<p>Continued From page 6</p> <p>Observation of the Preoperative Area in the Surgery Department on 10/10/06 at 10:00 AM revealed a refrigerator that contained in the side door compartment a 0.9 % saline solution 500 milliliter clear plastic bag for intravenous infusion with an expiration date that reads "June 06". Confirmation was made with the Director of Surgical Services at 10/10/06 at 10:10 AM.</p> <p>During tour of the Intensive Care Unit on 10/11/06 at 10:55 AM revealed a "Line Cart" located in front of the nurses desk that contained a 1 liter bottle of 0.9% saline solution with an expiration date of February 05. Further observation of the "Line Cart" revealed a 250 milliliter clear plastic bag labeled 5% Dextrose solution for intravenous infusion with an expiration date of January 05. Confirmation was made with the Intensive Care Unit/ Care Coordinator on 10/11/06 at 11:00 AM of the expired items.</p> <p>Review of the facility policy labeled "Outdated or Unusable Drugs (Return to Pharmacy)" Policy Number Rx-036 reads under the section labeled Procedure reads, "1. Whenever unusable or outdated drugs are found in the hospital, they will be returned to the Pharmacy for proper disposal." The facility policy labeled Out-Dated Drugs (Storage and Disposition) Policy Number Rx-037, reads "The Pharmacy stock and all drug storage areas in the hospital are checked monthly for out dated-drugs."</p> <p>Observation on 10/10/06 at 2:35 PM during a tour of the 4th Floor (East) unit clean supply room revealed three 5 liter bags of sterile water for irrigation with an expiration date of September 2006. The findings were confirmed in an</p>	H 706		

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H 708	Continued From page 7 interview with the medical/surgical director at this time. Continued observation of the 4th Floor medication Pyxis system at 2:55 PM revealed a locked medication refrigerator attached to the Pyxis that contained an opened, one-half full bottle of Citrate of Magnesia labeled Room 433B. An interview with the medical/surgical director at 3:05 PM on 10/10/06 revealed that the Patient had been discharged on 8/31/06. Observation on 10/11/06 at 11:40 AM during a tour of the postpartum unit clean supply room revealed the following expired drugs: One liter bag of Dextrose 5% in Water with an expiration date of September 2006. One liter bag of Dextrose 5% in 0.2% Sodium Chloride solution with an expiration date of September 2006. The above findings were confirmed in an interview with the director of women's services at this time.	H 708			
H 714	1200-8-1-.06 (7)(a) Basic Hospital Functions (7) Radiologic Services. (a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. This Statute is not met as evidenced by: Based on observations, interviews, and policy review the facility failed to ensure the safety of	H 714			

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H 714	Continued From page 8 one radiology employee. The findings included: Observations of the Radiology Department on October 11, 2006, revealed a Registered Nurse (RN#1) working in the Computed Tomography Room at 10:00 am, and in the Nuclear Medicine Room at 10:10 am, without a dose/film badge on his/her person. Interview with RN#1, at 10:00 am, on October 11, 2006, revealed the RN worked as a contract employee in Interventional Radiology, and had been employed at the facility for seven weeks. Interview with the Radiology Department Manager at 10:00 am, on October 11, 2006, confirmed RN#1 should have been wearing a dose/film badge. Review of the facility's Radiation Safety Operations Manual revealed all employees requiring dosimetry shall be issued a standard film badge and/or thermoluminescent dosimeter, and the exposure measurements will be recorded and kept on file.	H 714			
H 730	1200-8-1-.06 (9)(b) Basic Hospital Functions (9) Food and Dietetic Services. (b) The hospital must designate a person to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be: 1. A dietitian; or, 2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or,	H 730			

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H 730	Continued From page 9 3. A graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian. This Statute is not met as evidenced by: Based on review of employee records and staff interview, it was determined the facility failed to have a qualified food service director. The findings included: Review of the record for the Food Service Director revealed and interview, with this Employee the afternoon of 10/10/06, confirmed, the Employee was not enrolled in or had attended a 90 + hour food service supervision course.	H 730			
H 737	1200-8-1-.06 (9)(g) Basic Hospital Functions (9) Food and Dietetic Services. (g) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to patients with special dietary needs. This Statute is not met as evidenced by: Based on staff interviews, it was determined the facility exceeded the 14 hour lapse between supper and breakfast and did not provide a supplemental meal. The findings included:	H 737			

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H 737	Continued From page 10 Interview with the facility Food Service Director and shift manager, the morning of 10/10/06, confirmed the Supper was served at 4:15 PM and the Breakfast at 7 AM without a supplemental meal between those hours to the patients.	H 737		
H 739	1200-8-1-.06 (9)(i) Basic Hospital Functions (9) Food and Dietetic Services. (i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current "U.S. Public Health Service Food Service Sanitation Manual". This Statute is not met as evidenced by: Based on observation and staff interview, it was determined the dietary department was not maintained in a sanitary manner and cold food exceeded 41 degrees at the trayline. the findings included: Observation during the department tour, at 9:15 AM of 10/10/06, with the Food Service Director present, revealed the following ceiling vents and surrounding ceiling tiles had an accumulation of debris: between the grill and steamer; over the production table and steam jacketed kettle; in the dishroom on the dirty side, clean side and over the 3 compartment sink; by the reach-in refrigerators between the production and catering	H 739		

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H 739	Continued From page 11 sections and outside the diet office. Observation at 9:38 AM revealed the dishes were being processed and the 3 compartment sink was being used in the dishroom. Further observation during the tour revealed four cases of cups were stacked and a case of cup lids were stored on the floor of the paper storeroom. Observation during the mid-day meal trayline revealed a staff member taking and recording the food temperatures at 11:30 AM. Continued observation revealed the milk temperature was 43 degrees and served to the pureed textured diets. Interview, at 11:40 AM, with the shift manager revealed the person taking the temperatures was instructed to remove and replace any foods not in the appropriate temperature ranges.	H 739			

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P 001	1200-8-30 Initial This Statute is met as evidenced by: No deficiencies were cited as a result of the Pediatric Emergency Care Facility Survey completed on October 11, 2006.	P 001			

Division of Health Care Facilities

TITLE

(X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING 02 - STATE BUILDING B. WING _____	(X3) DATE SURVEY COMPLETED 10/10/2006
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H 872	1200-8-1-.08 (2) Building Standards (2) The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to maintain the hospital environment for the safety of both residents and staff as required by the Standard Regulation 1200-8-1-08(2) the NFPA 101, 8.5.5.2; 101, 8.5.5.3. The findings included: On 10-10-2006 at approximately 2:00 PM during inspection within the basement equipment room, observation revealed, there were penetrations in both the ceiling and the wall.	H 872		
H 874	1200-8-1-.08 (4) Building Standards. (4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities, and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are	H 874		

Division of Health Care Facilities

TITLE

(X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

DATE FORM

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H 874	Continued From page 1 conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to comply with the Regulatory Codes as required by the Standard Regulation 1200-8-1-08(4) and the Standard Building Code- SBC 1403.2.3. The findings included: On 10-10-2006 at approximately 1:45 PM during inspection within the basement area, observation revealed, a steel lintel carrying brick veneer over a doorway was missing. SBC 1403.2.3.	H 874		
H 893	1200-8-1-.08 (23) Building Standards. (23) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection, testing and observation, it was determined, the facility failed to maintain the negative air pressure within soiled areas as required by the Standard Regulation 1200-8-1-08(23) and the NFPA 90A; 90B-4; 101, 19. 5.2.1.	H 893		

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H 893	Continued From page 2 The findings included: On 10-10-2006 at approximately 2:30 PM during inspection within the men's bathroom in the Cath Lab area, testing revealed, the exhaust fan units were not working. Inspection and observation within the Medical Imaging area revealed, the return-air grilles were dusty. Inspection and observation within the elevator equipment room revealed, the exhaust fan unit was dusty. During inspection and observation within the dietary area, observation revealed, both air-return units and exhaust fan grilles were dusty.	H 893			
H 951	1200-8-1-.09 (1) Life Safety (1) Any hospital which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations. This Statute is not met as evidenced by: Surveyor: 16862 Based on inspection and observation, it was determined, the facility failed to comply with the applicable building and fire safety regulations as required by the Standard Regulation 1200-8-1-08(1), and the NFPA 10, 1.5.6; 55, 6.6; 70, 240-5; 70, 373-4; 410-56(d).	H 951			

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H 951	<p>Continued From page 3</p> <p>The findings included:</p> <p>On 10-10-2006 at approximately 12:30 PM during inspection within the basement shop area, observation revealed, the portable fire extinguisher was blocked with equipment. That was in violation of the NFPA 10, 1.5.6.</p> <p>Inspection within the storage area of the basement mechanical room revealed three pressurized cylinders which were not secured. Violation of the NFPA 55, 6.6.</p> <p>During inspection within the pain clinic of the Cath Lab area, observation revealed the use of an extension cord. NFPA 70, 240-5.</p> <p>During inspection on the 3rd floor next to the rehab area, observation within the electric panel room revealed, panels TA and TB both had unusual open space under the breakers. Violation of the NFPA 70, 373-4.</p> <p>During inspection within the basement mechanical equipment area, observation revealed a junction box without any cover plate.</p> <p>During inspection within the ceiling space above the east fire doors to the Cath Lab area, observation revealed, there was an open junction box without any cover plate.</p> <p>Inspection above the west fire doors of the Cath Lab revealed open junction box with loose wires. Those were in violation of the NFPA 70, 410-56(d).</p>	H 951		



Administrative Offices

October 24, 2006

Ms. Nina Monroe, Regional Administrator
State of Tennessee Department of Health
Bureau of Health Licensure and Regulation
Middle Tennessee Regional Office
710 Hart Lane, 1st Floor
Nashville, Tennessee 37247-0530

Dear Ms. Monroe:

The following information is provided in response to the recent state licensure survey completed on October 11, 2006 at Sumner Regional Medical Center.

ID Prefix Tag: H 404 1200-8-.04 (4) Administration

How SRMC will correct the deficiency: We will correct "no documentation on the transparent intravenous dressing" by following our policy and recording date and time of catheter insertion on the label provided in the IV starter kit and then attaching it to the IV dressing.

Who at SRMC will be responsible for correcting the deficiency: Director, Med/Surg

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking for this documentation.

How SRMC will correct the deficiency: We will correct failure to label medication and solutions both on and off the sterile field by following our stated policy and further educating our staff and anesthesiologists.

Who at SRMC will be responsible for correcting the deficiency: Director, Surgical Services, and Director Women's Services

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted to ensure compliance with re-education as needed.

How SRMC will correct the deficiency: We will ensure that all anesthesia carts are locked when not in use.

Who at SRMC will be responsible for correcting the deficiency: Director, Surgical Services, and Director Women's Services

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted to ensure compliance with re-education as needed.

How SRMC will correct the deficiency: We will correct "no documentation on the transparent intravenous dressing of Port-A-Cath" by following our policy and recording date and time of catheter insertion on the label provided in the IV starter kit and then attaching it to the IV dressing.

Who at SRMC will be responsible for correcting the deficiency: Director, Med/Surg

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking for this documentation.

ID Prefix Tag: H 647 1200-8-1-.06 (3)(i) 4 Basic Hospital Function

How SRMC will correct the deficiency: We will re-educate stocking personnel on the importance of accuracy of daily checks and ensuring that no items remain in stock after expiration date.

Who at SRMC will be responsible for correcting the deficiency: Director, Material Management

The date the deficiency will be corrected: November 1, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically looking at expiration dates to ensure compliance and immediate re-education as required.

ID Prefix Tag: H 665 1200-8-1-.06 (3)(o) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately correct and reeducate environmental services associates on proper cleaning of microwave ovens and bed side tables, and disposal of used cleaning materials.

Who at SRMC will be responsible for correcting the deficiency: Director, Environmental Services

The date the deficiency will be corrected: October 11, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically ensuring these deficiencies remain in compliance.

ID Prefix Tag: H 706 1200-8-1-.06 (6)(a) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately check all supply carts to ensure no expired solutions remain.

Who at SRMC will be responsible for correcting the deficiency: Director, Material Management

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all patient care areas specifically ensuring that expired items do not exist.

How SRMC will correct the deficiency: We will ensure that all medications belonging to a specific patient are removed when that patient leaves the hospital.

Who at SRMC will be responsible for correcting the deficiency: Director, Pharmacy

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Pyxis units are checked daily by Pharmacy staff. They will ensure this occurs. Spot checks will be conducted on all Pyxis units specifically ensuring that expired items or medications from previous patients do not exist.

ID Prefix Tag: H 714 1200-8-1-.06 (7)(a) Basic Hospital Functions

How SRMC will correct the deficiency: We will make sure that all Radiology Department associates wear a dose/film badge.

Who at SRMC will be responsible for correcting the deficiency: Director, Diagnostic Services

The date the deficiency will be corrected: October 11, 2006

How will SRMC prevent the same deficiency from happening again: Spot checks will be conducted in all diagnostic imaging areas specifically ensuring dose/film badges are worn by all associates working in that area.

ID Prefix Tag: H 730 1200-8-1-.06 (9)(b) Basic Hospital Functions

How SRMC will correct the deficiency: We will enroll the Director, Nutritional Service in a 90 hour food service supervisor course and make sure that he completes the course within two years.

Who at SRMC will be responsible for correcting the deficiency: Vice President, Support Services

The date the deficiency will be corrected: No later than October 11, 2008.

How will SRMC prevent the same deficiency from happening again: Vice President, Support Services will ensure that this requirement is added to the current contract as well as any future contracts and then annually reviewed for compliance.

ID Prefix Tag: H 737 1200-8-1-.06 (9)(g) Basic Hospital Functions

How SRMC will correct the deficiency: We will ensure that no more than 14 hours lapse between supper and breakfast.

Who at SRMC will be responsible for correcting the deficiency: Director, Nutritional Services

The date the deficiency will be corrected: November 20, 2006

How will SRMC prevent the same deficiency from happening again: By adjusting meal service hours on the inpatient floors, not exceeding 14 hours becomes the standard. Spot checks will monitor compliance.

ID Prefix Tag: H 739 1200-8-1-.06 (9)(i) Basic Hospital Functions

How SRMC will correct the deficiency: We will immediately clean and maintain cleanliness in all areas sited.

Who at SRMC will be responsible for correcting the deficiency: Director, Nutritional Services

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Daily inspections and spot checks. Note: State surveyor re-examined area on October 12, 2006 and verbally expressed her satisfaction with the previous night's cleaning.

How SRMC will correct the deficiency: Closer monitoring of the cold food temperatures in the tray line and meal preparation areas.

Who at SRMC will be responsible for correcting the deficiency: Director, Nutritional Services

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Daily inspections and spot checks.

ID Prefix Tag: H 872 1200-8-1-.08 (2) Building Standards

How SRMC will correct the deficiency: We will seal all penetrations in the wall and ceiling in the basement equipment room.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: November 30, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations as well as the Director, Safety and Security. Spot checks as part of the Environment of Care (JCAHO) continuous readiness.

ID Prefix Tag: H 874 1200-8-1-.08 (4) Building Standards

How SRMC will correct the deficiency: We will install a steel lintel carrying brick veneer over a doorway in the basement area.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: November 30, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations as well as the Director, Safety and Security. Spot checks as part of the Environment of Care (JCAHO) continuous readiness.

ID Prefix Tag: H 893 1200-8-1.08 (23) Building Standards

How SRMC will correct the deficiency: We will repair and clean exhaust fans in the Cath Lab, Medical Imaging, Elevator Equipment room and Dietary areas.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations, Director, Environmental Services, Director Nutritional Services

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again: Increased inspections and spot checks by appropriate Director.

ID Prefix Tag: H 951 1200-8-1-.09 (1) Life Safety

How SRMC will correct the deficiency: We will ensure that all portable fire extinguishers are readily available and not blocked from use.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will ensure that all pressurized cylinders are properly secured.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 12, 2006

How will SRMC prevent the same deficiency from happening again: Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will remove the extension cord in the Cath Lab and ensure that appropriate electrical outlets are available.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: November 30, 2006

SEP 15 14 42:36

Page 6 of 6
October 24, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will secure the open space under the breakers in electrical panel 3rd Floor, TA and TB.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will cover the junction box in the basement mechanical equipment area.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will cover the junction box in the ceiling space above the east fire doors to the Cath Lab.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

How SRMC will correct the deficiency: We will secure the loose wires and cover the junction box above the west fire doors of the Cath Lab.

Who at SRMC will be responsible for correcting the deficiency: Director, Plant Operations

The date the deficiency will be corrected: October 20, 2006

How will SRMC prevent the same deficiency from happening again:
Inspections by the Director, Plant Operations, and Director, Safety and Security.

Should you have any questions please contact Mr. Fred Levoy at 615 451-5529 or email; Fred.Levoy@Sumner.Org.

Sincerely,



R. Bruce James
Administrator

SUPPLEMENTAL #1

September 25, 2014
4:05pm

September 25, 2014

HAND DELIVERY

Jeff Grimm, Examiner
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Certificate of Need Application CN1409-041
Sumner Regional Medical Center –
Initiation of PET Service on Outpatient Campus of Hospital

Dear Mr. Grimm:

Responses to the questions in your letter dated September 19, 2014, are below. The required affidavit is enclosed at the end of this response. Please let us know if you need additional information.

1. Section A, Applicant Profile, Item 3

There appears to be an error with the phone number listed for the owner.

Response: A corrected page 1-R is attached as Attachment 1.

The registration of the owner with the Tennessee Secretary of State's Office is noted. Please also provide a copy of the Corporate Charter or Partnership Agreement.

Response: The document titled *Certificate of Formation* included with the original application is the formational document for Sumner Regional Medical Center, LLC.

Describe the existing ownership structure of Sumner Regional Medical Center, LLC and identify the members of the LLC with 5% or more ownership interest.

Response: The sole member of Sumner Regional Medical Center, LLC, is LifePoint Hospitals.

2. Section B, Project Description, Item I

The executive summary is noted. Based on the hospital's accreditation by the American College of Surgeons, what recommendations from the review were made with respect to adding PET as a diagnostic & treatment planning modality to meet clinical standards of care?

Response: The subject of PET capability was not raised by the American College of Surgeons during its last accreditation review of SRMC, and SRMC does not believe that that PET capability is an aspect of the accreditation criteria

Review of HSDA records revealed that the applicant had a previously approved CON for a mobile PET service on the main hospital campus 1 day per month focusing on use for diagnosing neurodegenerative disease, cerebrovascular accidents, brain tumors and seizure disorders (CN0406-058A). The mobile PET service was not unimplemented and surrendered to HSDA in December 2007. If SRMC could not implement the mobile PET service approved in CN0406-058A, what has changed that it needs a fixed stationary PET unit for cancer diagnosis per this proposed project? Please discuss.

Response: The prior certificate of need was not implemented because of financial problems at SRMC that ultimately lead to the bankruptcy of the organization and purchase of it by LifePoint. With the financial strength of LifePoint, SRMC now has the resources to establish and sustain a fixed PET service as explained in the application.

3. Section B, Project Description, Item II.A.

There appears to be an error in the Square Footage Chart. The construction cost in SF Chart amounts to \$455,990 but should be revised to \$460,000 in order to be consistent with the \$322.80 per SF cost and the \$460,000 entered in line item 5 of the Project Cost Chart. Please clarify.

Response: A revised Square Footage Chart is attached as Attachment 2.

4. Section B, Project Description, Item II.C

The need for the proposed PET service based on the absence of a PET service in Sumner & Macon Counties is addressed here, in the executive summary and the project specific criteria on page 13. In addition to the recap of the TDH report on cancer in Tennessee, the applicant may wish to consult with a program representative of TDH's Tennessee Cancer Coalition to further support the need for the proposed service. If possible, please document the suggestions or recommendations discussed with the TDH representative.

Response: It appears that the Cancer Coalition is not currently operational. An SRMC representative's telephone call to the number on the Cancer Center website was answered with a recorded message that the number is no longer in service. Emails to the contact person on the Cancer Coalition's website have not been answered.

The letter of support from Dr. Shipley, TN Oncology is noted, however, some estimate of referrals would be appreciated. Please provide letters from oncologists stating the estimated monthly PET referrals to SRMC.

Response: SRMC was unable to obtain letters with specific monthly estimates. As an alternative, SRMC is submitting at Attachment 3 a letter from Dr. Shipley confirming the SRMC's projected volumes are reasonable. Tennessee Oncology is the only oncology group with a presence in Gallatin.

In addition to identifying services of the oncology program such as radiation therapy, surgery and chemotherapy services; please provide additional information about SMRC's oncology program that provides a brief description of hospital/medical staff organizational structures for coordinating the activities of the oncology program, including information systems such as its tumor registry and tumor board; and a description of how the proposed PET service can contribute to SRMC's participation in any clinical investigative protocols through formal oncology network relationships with other providers.

Response: Cancer care at SRMC is under the leadership of its cancer committee. The cancer committee is responsible for goal setting, planning, initiating, implementing, evaluating, and improving all cancer-related activities. The care of the cancer patients requires a multidisciplinary approach and encompasses numerous physician and non-physician professionals. Required physician members are a diagnostic radiologist, pathologist, general surgeon, medical oncologist, and radiation oncologist. Required non-physician members include the program administrator, oncology nurse, social worker or case manager, certified tumor registrar (CTR), performance improvement or quality management professional. Additional physician or non-physician cancer committee members are required for specific categories, such as a hospice/home care nurse or administrator, pain control/palliative care physician specialist and cancer clinical research data manager or nurse. Additional members of the committee from time to time may include individuals from various disciplines such as dietary, pharmacy, pastoral care, mental health, or the American Cancer Society.

The number and types of physicians on staff at SRMC involved in cancer care are as follows:

- Radiation oncologist – 1 active staff; 10 coverage staff
- Medical oncologist – 2 active staff; 16 consulting/coverage staff
- General Surgeons – 4 active staff
- Urologists – 4 active staff
- Radiologists – 9 active staff
- Pathologists – 4 active staff

Information regarding the Cancer Conference (Tumor Board) is set forth in Attachment 4.

Tennessee Oncology is involved in various clinical investigations. Dr. Shipley has advised that she is not aware of any immediate, primary use of the PET service for clinical trials, but she believes the service will be of benefit in connection with the detection of cancer cells, thus supporting clinical trials conducted for treatments.

5. Section B, Project Description, Item II.E.

Please note that the equipment quote for the base fixed unit cost of \$1,093,866 expired in August 2014. Please provide an addendum or updated quote from the equipment vendor such that the offer will be in effect on the date that the application will be heard by HSDA (December 2014 at earliest).

Response: *The quote is dated August 29, 2014, but expires on November 21, 2014, which is the maximum time for which GE would provide a quote at the time. An updated quote effective through December 22, 2014, is attached as Attachment 5.*

Please identify the costs associated with the FDG/radioactive material, and identify the terms of the contractual arrangement that might apply with supplier(s), as necessary (a copy of a draft agreement or letter of interest between the applicant and the vendor would be helpful). Please also identify the address and distance to the closest cyclotron source. Are these costs reflected in the Project Cost Chart on page 20?

Response: *The cost of the radiopharmaceutical (FDG) used for PET scans is not a cost of the project, but is reflected as a supply cost in the Projected Data Chart. There is not initial investment or cost required to obtain these materials. Doses of FDG will be purchased on an as-needed basis when scans are scheduled.*

The supplier for FDG to Sumner Station will be Cardinal Health located in Nashville, at a cost of \$115 per dose. Cardinal Health is a provider of nuclear medicines to LifePoint hospitals under a long-standing vendor relationship, as confirmed by the letter at Attachment 6. Cardinal Health has its own cyclotron in Louisville, KY, a distance of approximately 160 miles.

6. Section C. Need Item 1. (Project Specific Criteria – PET Service)

Item 2 - it appears that the first sentence would apply to the project (accessible to 75% of the population of Sumner and Macon Counties). Please describe how the proposed PET/CT unit at Sumner Station meets this criterion.

Response: *Sumner and Macon counties constitute the primary service area for SRMC's other services, thus establishing that SRMC is accessible to the population. Sumner Station is in Gallatin; the other population center for Sumner County is Hendersonville, the center of which is about 10 miles from Sumner Station. The population of Lafayette, the population center for Macon County is about 35 miles from Sumner Station, but there is no other PET scanner closer than Sumner Station.*

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Item 3 - it is noted the applicant considered the possibility of a mobile PET unit. Given the proposed utilization that is more characteristic of the criterion for mobile units plus the applicant's previous unimplemented CN0406-058AW, what factors would have to be met to make a mobile service more attractive?

Response: A fixed PET has obvious advantages in terms of patient convenience. In addition, SRMC believes that a fixed PET will more acceptable to patients and referring physicians. In light of the current cost of a fixed PET unit, it is also economically advantageous to SRMC to purchase a fixed unit rather than pay a mobile vendor for use of equipment that would not be an SRMC asset. The PET unit will be capable of serving patients well beyond the 5-year period of depreciation. A mobile unit would be more attractive only if a fixed unit was not economically viable.

Item 6.c. - It is noted the service will be operated as a part of SRMC on its outpatient campus and is subject to the same emergency plan & procedures. Since this is a new service, how will the applicant handle emergencies specific to the PET/CT? What are the responsibilities of the medical director or on-site physicians for same?

Response: In the event of an emergency, the staff at the facility will call for an ambulance for transport to SRMC. The physician on site will be able to evaluate the patient and administer life-saving techniques if necessary.

Item 6.g. - the name of the entity that has issued permits for CT services was omitted from the response. While it is understood that a permit would be premature – please list the key requirements that must be met. In your response, it may be helpful to include as an addendum with the 8/15/14 letter from the architect for the project.

Response: The entity referenced is the Tennessee Division of Radiological Health. The Radiation Safety Officer at SRMC is familiar with the Division's rules applicable to this project, specifically, Chapter 0400-20-07 Standards for Protection Against Radiation and Chapter 0400-20-07 Use of Radionuclides in the Healing Arts. Copies of these regulations are not included because of their length, but key points are as follows:

- The PET/CT room will need to be appropriately shielded (radiation protection is referenced in the attachment to the architect's letter, Attachment C., Economic Feasibility – I in the original application).
- The facility will require a hot lab (included in the floor plan, Attachment B. IV in the original application).
- A Radioactive Materials License from the Division will be required.
- SRMC will need to form a Radiation Safety Committee for Sumner Station, which will establish policies and procedures required by the regulations referenced above.
- SMRC will need to appoint a Radiation Safety Officer for the Sumner Station campus.

**September 25, 2014
4:05pm**

7. Section C, Need, Item 5

Please identify the use of PET providers in Davidson County and other areas of TN by residents of Sumner and Macon County for the most recent 3 years. A suggested template is the table below showing utilization by Sumner residents. Please contact Alecia Craighead, HSDA Stat III for assistance with data from the HSDA Equipment Registry.

Response:

PET Utilization by Sumner County Residents, 2011-2013

Providers with PET Service	Provider Location	Distance from SRMC Sumner Station	2011	2012	2013	% Change '11-'13
Premier*	Davidson	26.5	47	**	12	(74.5)%
Imaging Alliance	Davidson	30.0	268	296	297	10.8%
TN Oncology	Davidson	27.7	274	246	234	(14.6)%
Centennial	Davidson	26.8	18	14	20	1.1%
VUMC	Davidson	27.0	93	131	120	29%
All other TN providers	Statewide		31	21	20	(35.5)%
Total – TN			731	708	703	(4)%

*Formerly Saint Thomas Midtown

**No data reported

8. Section C, Need, Item 6

Please summarize the strategies being implemented by SRMC other than the proposed relocation of the service that might help SRMC reach the 1,000 minimum utilization standards at some point within 5 years following project completion in October, 2016.

Response: The current PET market for Sumner and Macon is substantially below 1,000 scans annually, and it is uncertain if the volume of 1,000 scans per year will be achieved in the foreseeable future. However, SRMC notes that recent developments will likely lead to increased PET volumes. In 2013, CMS changed its coverage rules for PET, as summarized in Attachment 7. Specifically, there is now unconditional coverage for PET for 8 types of cancers for which special coverage determinations had to be made previously, and coverage is now approved for up to 3 PET scans for management of cancer involving anti-tumor treatment strategies. In any event, SRMC is proposing PET to complement existing cancer services and to make first-class diagnostic services conveniently accessible to patients in the community. SRMC has the resources to establish the service and the circumstances fit the criteria on the State Health Plan for special consideration.

Please identify the projected payor mix for the service in Year 1 as to # procedures and estimated gross revenue by payor in Year 1.

Response:

	<u>Scans</u>	<u>Gross Revenue</u>
Medicare	109	\$817,500
TennCare	16	\$120,000
Commercial	108	\$810,000
Self-pay	8	\$60,000

The methodology discussed on page 18 that identifies the utilization of the proposed PET service by Sumner & Macon County residents is noted. The projected increase in the “capture rate” (from 35% to 49% of 620 PET scans by residents of the PSA) appears to lead to a 40% increase in utilization from 241 procedures in Year 1 to 337 procedures in Year 2. What are the key factors that will determine whether or not the capture rate methodology is attainable?

Response: The original application incompletely and inaccurately explains SRMC’s assumptions regarding a 2 year ramp-up period. The PET market for Sumner and Macon counties averaged a total of 714 scans annually over the past 3 years. SRMC expects its portion of the PET market in Sumner and Macon counties ultimately will be similar to its portion of the radiation therapy market (49%). $49\% \times 714 = 350$. Assuming that 90% of the proposed scans will come from Sumner and Macon counties, the total expected PET volume at Sumner Station is 389. However, SRMC projected 241 scans in year 1 and 337 in year 2 to account for an extended ramp-up period, with the belief that it will achieve at least 49% market share in years 3 and beyond. The projections are conservative because they do not reflect likely increased volumes resulting from recent CMS coverage changes as referenced above. It should be noted that SRMC believes the assumption of 90% of scans from Sumner and Macon counties is also conservative, and it likely does not reflect the total potential for patients who reside in other counties but for whom Sumner Station is convenient.

9. Section C, Economic Feasibility Item 1 (Project Costs Chart) and Item 2 (funding)

Item 1 - the following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states “The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding.”

Is the \$1,498,728.00 fixed equipment cost listed in Line A.7 of the Project Cost Chart consistent with the Rule? In your response, please provide a breakout of the key cost items of the fixed unit that apply to the project per Agency Rule above. If not, please make the necessary equipment cost adjustments and submit a revised Project Cost Chart.

Response: The cost of the PET unit in the original application included the cost of equipment (\$1,093,866) and cost of maintenance for the first 5 years (\$404,862). There are no installation charges. However, the application did not include sales tax and freight charges, which total \$199,500. A revised Project Cost Chart is attached at Attachment 8. The applicant notes the total cost of the unit is below the dollar threshold of \$2 million to be classified as "major medical equipment."

Item 2 - Cash reserves are noted in the response, please confirm that this will serve as the source of the "sufficient resources" noted in the CFO's 9/9/14 letter.

Response: Yes.

10. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

Are the costs for professional fees related to image interpretation services included in the Chart? Please identify the amounts that apply to the project in Year 1.

Response: SRMC will not bill for, nor receive, professional fees. These services are billed separately by the radiologists.

Review of the Income Statement (YTD ending December 2013) in the attachments revealed differences from the Historical Data Chart (2013 column) such that net income appears to be understated in the application by approximately \$4.4 million. Please clarify.

Response: In the course of responding to this question, SRMC realized that it had included the incorrect Historical Data Chart that includes a small amount of non-hospital activity. A corrected Historical Data Chart is included as Attachment 9.

The difference of approximately \$4.4 million in 2013 net operating income in the corrected Historical Data Chart (\$6,406,000) and net income in the 2013 financial statement (\$10,647,021) is attributable to the following:

- The Historical Data chart includes \$4,152,000 for federal income taxes that are not in the internal financial statement because FIT is paid at the parent level. SRMC elected to include federal taxes in the Historical Data Chart as a more accurate representation of SRMC's financial results
- The Historical Data Chart does not include a one-time positive adjustment to income from rent in the amount of \$1,843,000, which is included in the financial statement. This item was excluded from the Historical Data Chart because it was a one-time adjustment and excluding it is consistent with historical consistency.
- The Historical Data Chart does not include interest as an expense, whereas the financial statement includes an interest expense allocation of \$1,754,000. SRMC elected not to include this allocation in the Historical Data Chart because it is not related to debt incurred by SRMC, but is an allocation of interest by the parent organization not reflective of financial results at SRMC.

11. Section C., Economic Feasibility, Item 6 B.

The detailed comparison to HSDA Equipment Registry PET charges and Medicare allowable rates for selected applications is noted. It appears that the Medicare allowable charges (net charges) average only 14% of the applicant's average gross charge compared to 25%, on average, for all payors. What accounts for the higher net charge in the projected data chart?

Response: SRMC's proposed charge of \$7,500 is based on pricing for PET services in LifePoint hospitals in other states that have fixed PET units. SRMC notes that the HSDA equipment registry data reflects considerable variability in PET charges in Tennessee.. For example, charges for PET at TriStar Centennial in 2013 averaged \$14,928 per scan, charges at Premier Radiology Midtown averaged \$8,499 in 2013 and charges at Vanderbilt averaged \$4,834.

What are the arrangements for professional fees related to imaging interpretation services by radiologists? Are these reflected in the projected Data Chart for the new service?

Response: Radiologists will bill for and receive their fees for interpretation services. These fees are not part of the project.

12. Section C, Economic Feasibility, Item 11 b.

The goals related to a more convenient and accessible site are noted. Looking at distance/travel times as a key factor, what are the savings in mileage/driving times to the proposed outpatient campus that residents of the service area could expect?

Response: The vast majority of patients in Sumner and Macon counties currently travel to one of the 5 Nashville providers. Most residents of Sumner County would experience a one-way drive of 25-30 miles that could require anywhere from 30-45 minutes depending on traffic. Most residents of Macon County now travel 60-70 miles one way to a Nashville provider, requiring 60-90 minutes depending on traffic. It should be noted that a significant proportion of cancer patients are over 65, and travel is burdensome to these patients, particularly travel to and in a large city like Nashville

What other key benefits should residents and their attending physicians be aware of in selecting SRMC's proposed PET service in lieu of other sites outside the service area?

Response: Patient convenience is the primary consideration. In addition, utilization of the PET at Sumner Station will contribute to SRMC's ability to maintain and evolve services in the community, thus making it possible for residents to receive more of their care closer to their homes.

13. Section C., Contribution to Orderly Development, Items 7 and 9

The copy of SRMC's licensure survey with plan of correction dated October 11, 2006 is noted. Review of the TDH website for licensed facilities revealed that SRMC's last

**September 25, 2014
4:05pm**

survey was in June 2008. Please provide a copy of same with the provider plan of correction (POC) and a copy of acceptance of the POC by TDH for this survey.

Response: The survey in June of 2008 occurred before SRMC's bankruptcy and acquisition by LifePoint. LifePoint has been unable to find its copy of the June 2008 survey and POC; however, SRMC was able to obtain from the Division of Health Care Facilities a copy of the survey. The Division could not locate a copy of SRMC's POC, but the Division provided copies of its Revisit Report forms, which confirm all cited deficiencies were corrected. Copies of the survey and Revisit Report documents are attached as Attachment 10.

14. Development Schedule

It appears that the earliest this application may be held with respect to the standard 60-day review cycle is December 17, 2014 in lieu of the November date entered on the form. Please revise the schedule.

Response: A revised schedule is included as Attachment 11.

Very truly yours,

BUTLER SNOW LLP



Dan H. Erood

clw
Attachments

September 25, 2014
4:05pmAFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DavidsonNAME OF FACILITY: Sumner Regional Medical Center

I, Ann H Erol, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

[Signature]
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 25th day of Sept., 2014,
witness my hand at office in the County of Davidson, State of Tennessee.

Sharron C. Couch
NOTARY PUBLIC

My commission expires _____

HF-0043

Revised 7/02



My Commission Expires MAR. 8, 2016

**September 25, 2014
4:05pm**

Attachment 3

September 25, 2014
4:05pm

TENNESSEE ONCOLOGY

www.tnoncology.com

MEDICAL ONCOLOGY/
HEMATOLOGY

Dianna L. Shipley, M.D.

Mathew J. Joseph, M.D.

Amy Cox, APRN-BC, AOCNP

Cyndi M. Adair, ACNP-BC

Re: Proposed PET at Sumner Station

Dear Mike:

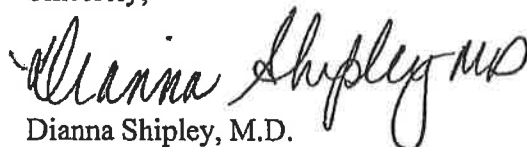
This will confirm our recent conversation regarding the certificate of need application filed by Sumner Regional to implement PET service at Sumner Station.

As you know Tennessee Oncology is the largest oncology group in Middle Tennessee and we serve more cancer patients in the region than any other group of physicians. We are the only oncology group with a presence in Gallatin.

It is my understanding that your planning for the PET service at Sumner Station assumes that your percentage of PET volumes from the Sumner County and Macon County market will be approximately the same as the percentage you currently have of the market for radiation therapy in the area, which is about 50%. Based on my knowledge of the services and patients in the market, I believe your assumption is valid, and I would expect that the PET service at Sumner Station would ultimately serve at least 50% of the patients from the region who need PET.

I hope this letter is helpful to your application.

Sincerely,



Dianna Shipley, M.D.

**September 25, 2014
4:05pm**

Attachment 4

September 25, 2014

4:05pm

Sumner Regional Medical Center Cancer Program

TITLE: CANCER CONFERENCE (Tumor Board)

POLICY: To provide routine multidisciplinary collaboration between clinicians for the purpose of providing comprehensive management for the oncology patient.

Sumner Regional Medical Center's Cancer Committee has approved cancer conferences to be held monthly. Cancer Conferences are integral to improving the care of cancer patients by contributing to the patient management process and outcomes and providing education to physicians and other staff in attendance.

Conference is available to all medical staff personnel and Allied Health personnel. Required attendance at conference is physicians responsible for the site being presented along with medical and radiation oncology, radiology, pathology, surgery and medicine.

PROCEDURE:

- The managing physician selects cases based on clinical importance from cases currently being managed. Case presentations include patients recently seen in consultation as well as patients being actively managed as an inpatient or on an outpatient basis.
- Cancer Registry personnel are responsible for coordinating and maintaining cancer conference documentation. Cancer conferences are scheduled in advance. A yearly calendar of scheduled conference dates is to be completed by the end of November as well as reserving meeting room.
- The number of cases discussed is proportional (15 % of annual analytic caseload)
- 15% of our annual analytic case load will be presented at cancer conference with 75% of these cases being prospectively.
- Discussion will include:
 1. Review of clinical evaluation, i.e., diagnostic imaging studies and pathology
 2. Appropriate case management based on clinical presentation and extent of patient's disease, performance status, and co-morbidity
 3. Accurate AJCC stage (either clinical stage or working stage) or other appropriate stage
 4. National Comprehensive Cancer Center Network (NCCN) treatment guidelines or other treatment guidelines developed by nationally recognized organizations, such as the American Cancer Society of Clinical Oncology (ASCO), should be considered when discussing treatment options where appropriate.
 5. 90% of all Physicians required to attend must meet this percentage. Medical Oncology, Radiation Oncology, Radiology, Pathology, Surgery and Cancer Registry.
 6. A conference grid is maintained by the Cancer Registry to accurately monitor conference frequency (monthly), multidisciplinary attendance, total case presentation, the rate of prospective cases presentation, Options for clinical trial participation.

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4:05pm

7. Conference grid includes documentation of the fact that AJCC staging or other appropriate staging was discussed, where appropriate.
8. Cancer Conference activities are reported by the Cancer Conference Coordinator to the Cancer Committee at least quarterly.

Conference documentation includes:

1. Date of meeting
2. Sites discussed/Prospective-retrospective
3. Physician attendance
4. Non-physician attendance
5. Clinical Staging and National Treatment guidelines reviewed and care plan consistent with guidelines
6. Eligible for clinical trials
7. Agenda for Cancer Conference provided to physicians

DISTRIBUTION: Cancer Program
APPROVAL: Cancer Committee
REVIEWED: 01/03; 01/05; 01/06; 02/07, 2/08, 2/10,2/14
REVISED: 1/04, 01/09
ORIGINAL: 2002

**September 25, 2014
4:05pm**

Attachment 6

210 25th Ave N, Ste 131
Nashville, TN 37203
615-327-3356 (phone)
615-320-0431 (fax)

September 25, 2014
4:05pm



September 23, 2014

To whom it may concern:

Cardinal Health will provide unit dose F-18 FDG doses to Sumner hospital and any of its affiliates according to the Healthtrust Purchasing Group contract available to any Lifepoint facility per Lifepoint's signed agreement with Cardinal Health. The current contract price is \$115 per unit dose.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Marsh".

Kevin Marsh

GE Healthcare

September 25, 2014
4:05pm

Medicare National Coverage for Positron Emission Tomography (FDG) for Solid Tumors

Summary of the Coverage Policy

On June 11, 2013, the Centers for Medicare & Medicaid Services (CMS) posted a final national coverage decision (NCD) memorandum that announced two important coverage policy revisions for FDG PET for solid tumors:¹

1. CMS will end coverage with evidence development (CED) that had previously been required for several cancer indications when using FDG PET to inform initial and/or subsequent Anti-tumor Treatment Strategies (ATS).
2. CMS will cover three FDG PET scans when used to guide subsequent management of ATS after completion of initial anti-cancer therapy for any cancer indication. Additional coverage of FDG PET scans beyond the three scans will be determined by local Medicare Administrative Contractors (MACs).

The first coverage policy revision changes the following cancers from the status of "coverage with evidence development" to "covered": brain, cervix (uteri), small cell lung, soft tissue sarcoma, pancreas, testes, prostate,² thyroid, and all other cancers not specifically listed. Consequently, physicians will be

reimbursed for ATS PET studies for these cancers without having to supply data to the National Oncologic PET Registry (NOPR). This change reflects CMS's determination that current evidence is adequate to conclude that the results of FDG PET scans will guide physicians in managing the subsequent ATS of Medicare beneficiaries who have completed an initial treatment regimen. Table 1 summarizes CMS coverage policy for FDG PET studies for solid tumors.

The second coverage policy revision specifies the number of FDG PET scans that Medicare will cover to guide subsequent management of ATS for all solid tumor cancers. The revised national coverage policy allows for coverage of three FDG PET scans; however, CMS recognizes that a patient who has not been successfully treated with initial anti-tumor therapy might be a candidate for 'second line' or even further treatment, and there might be instances where additional FDG PET scans -- beyond three -- can be appropriately informative, depending on pertinent facts that can be found in the patient's medical documentation. For this reason, CMS will now permit local MACs to determine coverage for additional FDG PET scans beyond three that are automatically covered by this new policy.



Table 1. Changes in Medicare National Coverage for FDG PET for Solid Tumors

Tumor Type	Before June 11, 2013		After June 11, 2013	
	Initial Treatment	Subsequent Treatment	Initial Treatment	Subsequent Treatment
Colorectal	Cover	Cover	Cover	Cover
Esophagus	Cover	Cover	Cover	Cover
Head and Neck (not thyroid CNS)	Cover	Cover	Cover	Cover
Lymphoma	Cover	Cover	Cover	Cover
Non-small cell lung	Cover	Cover	Cover	Cover
Ovary	Cover	Cover	Cover	Cover
Brain	Cover	CED	Cover	Cover
Cervix	Cover/CED ¹	Cover	Cover ²	Cover
Small cell lung	Cover	CED	Cover	Cover
Soft tissue sarcoma	Cover	CED	Cover	Cover
Pancreas	Cover	CED	Cover	Cover
Testes	Cover	CED	Cover	Cover
Prostate	Non-cover	CED	Non-cover	Cover
Thyroid	Cover	Cover/CED ³	Cover	Cover
Breast (male and female)	Cover ⁴	Cover	Cover ⁵	Cover
Melanoma	Cover ⁶	Cover	Cover ⁷	Cover
Myeloma	Cover	Cover	Cover	Cover
All other solid tumors	Cover	CED	Cover	Cover
All other cancers not listed	CED	CED	Cover	Cover

¹Nationally non-covered for diagnosis of cervical cancer. Covered for the detection of pre-treatment metastases in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. All other uses are CED.

²Non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are covered.

³Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are CED.

⁴Non-covered for diagnosis and/or initial staging of axillary lymph nodes. Covered for initial staging of metastatic disease.

⁵Non-covered for initial diagnosis and/or staging of axillary lymph nodes. Covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy are covered.

⁶Non-covered for initial staging of regional lymph nodes. All other uses for initial staging are covered.

⁷Non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy are covered.

Implications for the National Oncology PET Registry (NOPR)

This national coverage policy revision removes the requirement for prospective data collection by the NOPR for those cancers or cancer types that had been covered under CED and are now listed as covered. That is, NOPR will no longer accept new FDG case registrations effective June 12, 2013. However, NOPR will still continue for NaF-PET which is addressed in a separate national coverage policy.^{3,4}

Definitions

"National Coverage Determinations (NCD)" are developed by CMS to describe the nationwide conditions for Medicare coverage for a specific item or service.⁵ Once published, an NCD is binding on all Medicare Administrative Contractors (MACs) and Medicare Advantage (Part C) health plans.

"Local Coverage Determinations (LCDs)" are decisions published by local MACs on whether to cover a particular service in its regional jurisdiction.⁶ LCDs may be developed in

the absence of an NCD or as a supplement to an NCD as long as the LCD policy does not conflict with national policy.

"Coverage with Evidence Development (CED)" is a coverage decision made through an NCD.⁷ This type of NCD requires additional data collection (e.g., data collected in a clinical trial or registry) as a condition of coverage. The purpose of CED is to provide Medicare coverage for a particular item or service and to develop evidence of its impact on the health of Medicare beneficiaries.

"FDG PET" refers to PET imaging utilizing FDG as the radioactive tracer (2-deoxy-2-[18F]-fluoro-D-glucose, also known as 18F fluorodeoxyglucose). CMS includes integrated FDG PET/computerized tomography (FDG PET/CT) and integrated FDG PET/magnetic resonance imaging (FDG PET/MRI) in the term FDG PET.

"Completion of initial anticancer therapy" denotes the conclusion of the first treatment regimen implemented for the elimination or control of a patient's cancer following its diagnosis. A treatment regimen could include multiple 'therapies' (such as chemotherapy, radiotherapy, and/or cancer surgery) in combination. The completion of initial anticancer therapy (that is, the conclusion or termination of all anticancer therapies in the initially intended (combination) treatment regimen) marks, in time, the starting point of subsequent ATS planning (and the completion of initial ATS planning). Note: CMS does not consider 'watchful waiting' as a therapy to be included in an initial treatment regimen.

Frequently Asked Questions

1. Do Medicare revisions to its NCD for FDG-PET for cancer affect the reimbursement amount received by providers?

Answer: No. Coverage determinations specify the patient conditions, and diagnostic testing or treatment pre-requisites Medicare requires for a patient to qualify to receive an FDG-PET scan. Medicare reimbursement amounts are unchanged by revisions in coverage policies and are published in separate Medicare regulations.

2. Does the Medicare NCD for FDG-PET for cancer affect coverage by commercial payers?

Answer: No, not directly. Commercial payers have their own internal processes and criteria for making or revising coverage policies. However, most commercial payers monitor Medicare coverage decisions and some may be influenced by Medicare coverage policy decisions in the development or revision of their own policies.

3. How does the Medicare NCD for FDG-PET for cancer affect coverage of FDG-PET for cardiac or neurological conditions?

Answer: Medicare's NCD for FDG-PET for cancer does not impact coverage of FDG-PET for any other type of indication, e.g. cardiac or neurological. Medicare has separate coverage policies for these other indications.

4. Does the Medicare NCD for FDG-PET for cancer apply to combination PET technologies, such as PET/CT and PET/MRI?

Answer: Yes. In this coverage decision, CMS includes integrated FDG PET/computerized tomography (FDG PET/CT) and integrated FDG PET/magnetic resonance imaging (FDG PET/MRI) in the term FDG PET.

5. How does Medicare's NCD for FDG-PET affect reporting of PET scans to the National Oncology PET Registry?

Answer: The Medicare NCD for FDG-PET for Solid Tumors calls for the end of the prospective data collection requirements under CED for all oncologic indications for FDG-PET. Please note that this decision applies to the FDG-PET registry established in 2009 (NOPR-2009) only. Effective June 12, 2013, the NOPR-2009 registry will no longer accept new case registrations. However, the NOPR registry to study NaF-18 PET to identify bone metastasis of cancer will remain open.⁸

6. Who determines coverage for FDG-PET for Medicare patients with cancer who need more than three follow-up PET scans?

Answer: Local MACs have the discretion to determine whether additional FDG-PET scans (beyond three) are reasonable and medically necessary for Medicare patients who have cancer. The patient's physician will likely need to submit written documentation to the MAC to establish the medical necessity of the procedure for the particular patient circumstance.

¹CMS. Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R4). June 11, 2013. <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=263> accessed 6/19/13.

²Prostate cancer remains non-covered for initial treatment strategy.

³CMS. National Coverage Determination (NCD) for Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (220.6.19). <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=336&ncdver=1&bc=AgAAQAAAAAAAAA%3d%3d&> accessed 6/19/13

⁴National Oncology PET Registry News. <http://www.cancerpetregistry.org/news.htm#June0112013> accessed 6/19/13

⁵CMS. Innovators' Guide to Navigating Medicare. 2010. pp. 11-13. http://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf, Accessed 6/19/13.

⁶Ibid.

⁷Ibid.

⁸National Oncology PET Registry. NOPR Update: Closing of FDG PET Data Collection. (June 11, 2013). <http://www.cancerpetregistry.org/news.htm>

September 25, 2014
4:05pm

September 25, 2014
4:05pm

Attachment 7

**September 25, 2014
4:05pm**

Attachment 10

September 25, 2014
4:05pm

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING: 01 - MAIN BUILDING B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 871	<p>1200-8-1-.08 (1) Building Standards</p> <p>(1) The hospital must be constructed, arranged, and maintained to ensure the safety of the patient.</p> <p>This Rule is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to comply with the life safety codes.</p> <p>The findings included:</p> <p>On 6/25/08 at approximately 3:00 PM< inspection of the 3rd floor physical therapy handicapped bathroom, the handicapped whirl pool treatment room and the handicapped admitting bathroom revealed no strobe lights. ADA I</p> <p>Inspection of the 4th floor clean storage room north revealed a stained ceiling tile TDOH 1200-8-1-.08</p> <p>On 6/26/08 at approximately 8:00 AM, inspection of the handicapped bathroom in the admitting area revealed a broken ceiling tile. TDOH 120-8-1-.08</p>	H 871			

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

07/14/08

September 25, 2014

4:05pm

State Form: Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number TNP531116	(Y2) Multiple Construction A. Building 01 - MAIN BUILDING B. Wing	(Y3) Date of Revisit 9/4/2008
Name of Facility SUMNER REGIONAL MEDICAL CENTER	Street Address, City, State, Zip Code 555 HARTSVILLE PIKE GALLATIN, TN 37066	

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix H0871 Reg. # 1200-8-1-.08 (1) LSC	Correction Completed 08/10/2008	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed
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ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By State Agency	Reviewed By	Date:	Signature of Surveyor:	Date:
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:
Followup to Survey Completed on: 6/26/2008		Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/23/2014

FORM APPROVED

OMB NO. 0938-2891
September 25, 2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - MAIN BUILDING B. WING _____		(X3) DATE SURVEY COMPLETED 4:05pm 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
K 025	<p>NFPA 101 LIFE SAFETY CODE STANDARD</p> <p>Smoke barriers are constructed to provide at least a one half hour fire resistance rating in accordance with 8.3. Smoke barriers may terminate at an atrium wall. Windows are protected by fire-rated glazing or by wired glass panels and steel frames. A minimum of two separate compartments are provided on each floor. Dampers are not required in duct penetrations of smoke barriers in fully ducted heating, ventilating, and air conditioning systems. 19.3.7.3, 19.3.7.5, 19.1.6.3, 19.1.6.4</p> <p>This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the smoke doors.</p> <p>The findings included:</p> <p>On 6/25/08 at approximately 12:00 Pm, inspection of the area above the smoke doors by room 429 revealed a penetration around a 1-inch conduit (2/5/8 inch dry wall). NFPA 101, 8.2.4.4.1</p> <p>Inspection of the corridor wall above the ceiling by the 2nd floor sleep room revealed an i-inch hole in the wall (2 5/8 inch dry wall). NFPA 101, 8.2.4.4.2</p>	K 025			
K 029	<p>NFPA 101 LIFE SAFETY CODE STANDARD</p> <p>One hour fire rated construction (with ¾ hour fire-rated doors) or an approved automatic fire extinguishing system in accordance with 8.4.1 and/or 19.3.5.4 protects hazardous areas. When</p>	K 029			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

07/14/2008

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See Instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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K 029	Continued From page 1 the approved automatic fire extinguishing system option is used, the areas are separated from other spaces by smoke resisting partitions and doors. Doors are self-closing and non-rated or field-applied protective plates that do not exceed 48 inches from the bottom of the door are permitted. 19.3.2.1 This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the hazardous areas. The findings included: On 6/26/08 at approximately 9:00 AM, inspection of the 2nd floor electrical room revealed a 8 inch hole in the wall (2 5/8 inch dry wall). NFPA 101, 19.3.2.1	K 029			
K 052	NFPA 101 LIFE SAFETY CODE STANDARD A fire alarm system required for life safety is installed, tested, and maintained in accordance with NFPA 70 National Electrical Code and NFPA 72. The system has an approved maintenance and testing program complying with applicable requirements of NFPA 70 and 72. 9.6.1.4	K 052			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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OMB NO 0938-0091
September 23, 2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - MAIN BUILDING B. WING _____		(X3) DATE SURVEY COMPLETED 4:05pm 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
K 052	Continued From page 2 This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the alarm system/. The findings included: On 6/25/08 at approximately 1:00 PM, inspection of the facility revealed pull stations were mounted above the 54-inch rule on 1st, 2nd, 3rd, and the basement floors. NFPA 72, 2-8-1 Inspection of the 2nd floor C- section, the surgery recover area, and the basement light room revealed the pull stations were blocked with equipment. NFPA 72, 2-8.2.1	K 052			
K 054	NFPA 101 LIFE SAFETY CODE STANDARD All required smoke detectors, including those activating door hold-open devices, are approved, maintained, inspected and tested in accordance with the manufacturer's specifications. 9.6.1.3 This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the smoke detectors. The findings included: On 6/25/08 at approximately 2:00 PM, inspection of the facility revealed smoke detectors were too close to the air diffusers and the air return vents on 1st, 2nd, 3rd, and the basement floors. NFPA 72, 2-8-2-1	K 054			

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NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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K 062	<p>NFPA 101 LIFE SAFETY CODE STANDARD</p> <p>Required automatic sprinkler systems are continuously maintained in reliable operating condition and are inspected and tested periodically. 19.7.6, 4.6.12, NFPA 13, NFPA 25, 9.7.5</p> <p>This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the sprinkler system.</p> <p>The findings included:</p> <p>On 6/25/08 at approximately 1:00 PM, inspection of the 2nd floor nursery area and in the morgue area revealed escutcheon plates were missing. NFPA 13, 3.2.7.2</p> <p>Inspection of the kitchen area revealed the sprinkler heads were corroded. NFPA 13, 3.2.6.1</p>	K 062			
K 064	<p>NFPA 101 LIFE SAFETY CODE STANDARD</p> <p>Portable fire extinguishers are provided in all health care occupancies in accordance with 9.7.4.1. 19.3.5.6, NFPA 10</p> <p>This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the fire extinguishers.</p> <p>The findings included:</p>	K 064			

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4:05pm

NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
K 064	Continued From page 4	K 064		
	On 6/25/08 at approximately 12:30 PM, inspection of the corridors by rooms 404, 405, break room 3 north, and the 1st floor wound care area revealed fire extinguishers were not checked monthly. NFPA 10, 4.3.1			
	Inspection of the 1st floor lab, the medical records office, and the basement wood shop revealed the fire extinguishers were blocked with equipment. NFPA 10, 1.6.3			
K 067	NFPA 101 LIFE SAFETY CODE STANDARD	K 067		
	Heating, ventilating, and air conditioning comply with the provisions of section 9.2 and are installed in accordance with the manufacturer's specifications. 19.5.2.1, 9.2, NFPA 90A, 19.5.2.2			
	This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the HVAC system.			
	The findings included:			
	On 6/25/08 at approximately 1:45 PM, inspection of 2 north and 2 west soiled utility rooms revealed the exhaust fans were not working. NFPA 101, 19.5.2.1			
	Inspection of the basement elevator room revealed the exhaust fan vent cover was dirty. NFPA 101, 19.5.2.1			
K 141	NFPA 101 LIFE SAFETY CODE STANDARD	K 141		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - MAIN BUILDING B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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K 141	Continued From page 5 Non-smoking and no smoking signs in areas where oxygen is used or stored are in accordance with 19.3.2.4, NFPA 99, 8.6.4.2. This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the no smoking signs. The findings included: On 6/25/08 at approximately 12:30 PM, inspection of the 3rd floor physical therapy storage room and room 303 revealed cylinders of oxygen being stored and no precautionary signs posted. NFPA 99, 8.6.4.2	K 141			
K 147	NFPA 101 LIFE SAFETY CODE STANDARD Electrical wiring and equipment is in accordance with NFPA 70, National Electrical Code. 9.1.2 This STANDARD is not met as evidenced by: Based on observation and inspection, it was determined the facility failed to maintain the electrical system. The findings included: On 6/25/08 at approximately 1:15 PM, inspection of the 3rd floor rehab therapy office and the 2nd floor laxation room revealed electrical outlets next to the sinks were not ground fault circuit interrupters (GFCI). NFPA 70, 210-8-(a)(5)	K 147			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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OMB NO. 0938-0691

September 25, 2014

(X3) DATE SURVEY COMPLETED 4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - MAIN BUILDING B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
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K 147	Continued From page 6 On 6/26/08 at approximately 6:30 AM, inspection of the 1st floor nurses' administers' office, the er area, the lab, and in the EDS area revealed electrical panels were blocked with equipment. NFPA 70, 110-26(a) Inspection of the 1st floor emergency rooms revealed the emergency electrical outlets were not labelled with the electrical panels. NFPA 70, 517-19(a) Inspection of the kitchen area and the basement laundry area revealed not all of the electrical outlets were ground fault circuit interrupters (GFCI). NFPA 70, 517-20	K 147			

Post-Certification Revisit Report

September 25, 2014

4:05pm

Public reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number 440003	(Y2) Multiple Construction A. Building 01 - MAIN BUILDING B. Wing	(Y3) Date of Revisit 9/4/2008
Name of Facility SUMNER REGIONAL MEDICAL CENTER		Street Address, City, State, Zip Code 555 HARTSVILLE PIKE GALLATIN, TN 37066

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the Identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix _____ Reg. # NFPA 101 LSC K0025	Correction Completed 06/26/2008	ID Prefix _____ Reg. # NFPA 101 LSC K0029	Correction Completed 07/18/2008	ID Prefix _____ Reg. # NFPA 101 LSC K0052	Correction Completed 07/15/2008
ID Prefix _____ Reg. # NFPA 101 LSC K0054	Correction Completed 08/10/2008	ID Prefix _____ Reg. # NFPA 101 LSC K0062	Correction Completed 08/10/2008	ID Prefix _____ Reg. # NFPA 101 LSC K0064	Correction Completed 07/14/2008
ID Prefix _____ Reg. # NFPA 101 LSC K0067	Correction Completed 08/10/2008	ID Prefix _____ Reg. # NFPA 101 LSC K0141	Correction Completed 08/10/2008	ID Prefix _____ Reg. # NFPA 101 LSC K0147	Correction Completed 08/10/2008
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed

Reviewed By _____ State Agency	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____
Reviewed By _____ CMS RO	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____

Followup to Survey Completed on: 6/26/2008	Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/23/2014

FORM APPROVED

September 25, 2014

OMB NO. 0938-0291
(X3) DATE SURVEY COMPLETED 4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 385	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on observation, policy review and interview it was determined the hospital's nursing services failed ensure patient safety by not adhering to approved policies and procedures concerning 1 of 1 Malignant Hyperthermia carts. The findings included: The hospital failed to ensure an effective method for the storage and administration of medications used to treat Malignant Hyperthermia in accordance with the approved medical staff policies and procedures for 1 of 1 Malignant Hyperthermia carts. (REFER TO A 405)	A 385			
A 405	482.23(c)(1) ADMINISTRATION OF DRUGS All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.	A 405			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

07/14/2008

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the Institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/23/2014
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OMB NO. 0938-0891
September 26, 2014
(X3) DATE SURVEY COMPLETED 4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 405	Continued From page 1 This STANDARD is not met as evidenced by: Based on policy review, observation, and interview, it was determined the hospital failed to ensure an effective method for the storage and administration of medications used to treat Malignant Hyperthermia in accordance with approved medical staff policies and procedures for 1 of 1 Malignant Hyperthermia carts. The findings included: Review of the facility's "Malignant Hyperthermia Protocol" policy with a review date of May 2008 revealed the following documentation: "O.R. [Operating Room] will have supplies available to manage malignant hyperthermia...Malignant hyperthermia is a potentially fatal syndrome that can affect patients of any race and gender, particularly the young. It can occur in the O.R. and/or later in the PACU, as well as, any time in the immediate post-operative course...SUPPLIES: Immediately available on malignant hyperthermia emergency cart:...Dantrolene (36 amps)." Review of the facility's "Malignant Hyperthermia Cart" policy revised May 2008 revealed the following documentation: "1. The malignant hyperthermia cart will be checked by the R.N. [Registered Nurse] in surgery once a month to make sure all necessary medications and supplies...are present and in date...Medicine drawer checked daily Monday through Friday on regular workdays and on weekends and holidays	A 405			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/23/2014
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SEP 25, 2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 666 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 405	<p>Continued From page 2</p> <p>if OR is called in...3. A copy of malignant hyperthermia protocol reviewed annually is located on top pf the cart. Instructions on dosage and administration of the individual medications are kept in the drawers with the meds they pertain to...The malignant hyperthermia care is located in the O.R. holding area and kept locked at all times."</p> <p>Observation on 6-25-08 in the main Operating Room at 10:50 AM revealed the Malignant Hyperthermia Cart contained only 30 vials of Dantrolene (a medication used to treat Malignant Hyperthermia/a biochemical chain reaction response " triggered " by commonly used general anesthetics. General signs of the MH crisis include a rise in heart rate, increased body metabolism, muscle rigidity and/or fever that may exceed 110 degrees F. Complication include: cardiovascular collapse, brain damage, internal bleeding or failure of other body systems. This is a potentially fatal syndrome.). During an interview at 10:55 AM the Director of Surgical Services revealed that the 30 vials were all that were ever on the cart. Further observation revealed no instructions were available on how to use the Dantrolene.</p> <p>During an interview on 6-25-08 at 2:50 PM the Director of Pharmacy Services alleged 6 vials of Dantrolene were in the Recovery Room (PACU). Observation at 3:00 PM in the PACU revealed there were no vials of Dantrolene present. This finding was confirmed by the Vice President of Clinical Services.</p> <p>On 6/25/08 at 3:15 PM, interview with 2 nurses in the Cardiac Care Unit revealed no Dantrolene was kept in that department. This was also</p>	A 405			

PRINTED: 09/23/2014

FORM APPROVED

September 23, 2014

4:05pm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 405	Continued From page 3 confirmed by the Vice President of Clinical Services during observation and interview. On 6/25/08 at 3:25 PM the Director of Pharmacy Services stated to the surveyor and the Vice President of Clinical Services that the other 6 vials were in the Labor and Delivery Department (L&D). The Director further stated "it used to be in the PACU but I forgot it is now in the L&D." Observation in the L&D at 3:40 PM revealed there were 6 vials of Dantrolene in the L&D Pixes (medication cart). No instructions for the use of the Dantrolene were found at the time of observation. Interview with the Director of the Women's Center on 6-26-08 at 10:00 AM confirmed that there were no instructions on use of the medication in the cart, and the Director further stated when asked where the instructions were "I guess we would look in the policy manual."	A 405			
A 457	482.24(c)(1)(iii) VERBAL ORDERS AUTHENTICATED BASED ON LAW All verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours. This STANDARD is not met as evidenced by: Based on policy review and record review it was determined the facility failed to ensure verbal orders from physicians were signed by those physicians in a timely manner for three patients	A 457			

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OMB NO. 0938-0291

September 26, 2014 4:05pm

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003		(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008	
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
A 457	<p>Continued From page 4 (#31, #34, #39) of 40 patient records sampled.</p> <p>The findings include:</p> <p>Review of the facility's "Physician's Order: Verbal/Phone/Copied" policy revised February 2005 revealed the policy did not designate a time frame for physician signature.</p> <p>Medical record review revealed Patient #31 revealed the patient was admitted to the facility on 06/12/08. On 06/12/08 a verbal order was written at 2140 for "Ambien 10 milligrams, one dose now." A later untimed verbal order on 06/12/08 was written for "Normal saline flush each shift and as needed." These orders were not signed by the ordering physician as of the survey date of 06/26/08.</p> <p>Medical record review for Patient #34 revealed the patient was admitted to the facility on 06/11/08. On 06/11/08 the Anesthesia Preoperative Standing Orders were signed by the CRNA [Certified Registered Nurse Anesthetist] but were not signed as of the survey date of 06/26/08 by the attending physician. This included medication orders for "Versed 2 mg [milligrams] IV [intravenously]; Robinul 0.1 mg IV; Pepcid 20 mg IVPB[intravenously per bag]; Reglan 10 mg IV."</p> <p>Medical record review for Patient #39 revealed the patient was admitted to the facility on 06/09/08. On 06/09/08 the Physician Standing Order - OR form was signed by the Registered Nurse but there was no physician's signature on the orders as of the survey date of 06/26/08. The orders included "IV 1000 ml normal saline with 50,000 units Bacitracin; Thrombin 20,000 units."</p>			A 457			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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September 23, 2014

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 466	<p>482.24(c)(2)(v) CONTENT OF RECORD - INFORMED CONSENT</p> <p>[All records must document the following, as appropriate:] Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.</p> <p>This STANDARD is not met as evidenced by: Based on policy review and review of medical records it was determined the facility failed to adhere to its policy by not obtaining an informed consent for one patient (#5) of 40 patient's sampled.</p> <p>The findings include:</p> <p>Review of the facility's "Consents for Treatment" policy revised June 2008 revealed the following documentation: "A consent for medical treatment is obtained for each patient treated in the hospital... TYPES OF CONSENTS: 1. General consent for treatment - signed on each admission and witnessed...In the event that consent cannot be obtained from the adult patient and there is no legal guardian the following is a list of who may give consent in order of priority: 2. Adult children..."</p> <p>Medical record review revealed Patient #5 was admitted to the Emergency Department on 04/20/08 at 0948 with complaints of rash with itching all over and nausea. The patient had blood drawn, received an EKG[electrocardiogram] and CT [computerized tomography] while in the</p>	A 466			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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OMB NO. 0938-0891
September 25, 2014
4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 466	Continued From page 6 Emergency Department. The patient was accompanied by a daughter. The "Authorization for Treatment and Assignment of Benefits" form was not signed by the patient or the daughter. On the form it is documented "Pt.[patient] discharged before signing." The patient's signature was on the "Discharge Instructions". The patient was discharged at 1310.	A 466			
A 490	482.25 PHARMACEUTICAL SERVICES The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. This CONDITION is not met as evidenced by: Based on policy review, observation and interview it was determined the hospital's pharmaceutical services failed to meet the needs of the patients by not following developed policies and procedures for availability and instructions for use for medication to treat Malignant Hyperthermia and by not ensuring unusable medications were not available for use by facility staff.	A 490			

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NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 490	Continued From page 7 The findings included: 1. Based on policy review, observation, and interview, it was determined the hospital pharmacist failed to ensure adequate supervision of drug storage and use procedures according to facility policy and procedure for 1 of 1 Malignant Hyperthermia carts. (REFER TO A 492)	A 490			
A 492	482.25(a)(1) PHARMACIST RESPONSIBILITIES A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services. This STANDARD is not met as evidenced by: Based on policy review, observation, and interview, it was determined the hospital pharmacist failed to ensure adequate supervision of drug storage and use procedures according to facility policy and procedure for 1 of 1 Malignant Hyperthermia carts. The findings included: Review of the facility's "Malignant Hyperthermia Protocol" policy with a review date of May 2008	A 492			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 492	<p>Continued From page 8</p> <p>revealed the following documentation: "O.R. [Operating Room] will have supplies available to manage malignant hyperthermia...Malignant hyperthermia is a potentially fatal syndrome that can affect patients of any race and gender, particularly the young. It can occur in the O.R. and/or later in the PACU, as well as, any time in the immediate post-operative course...SUPPLIES: Immediately available on malignant hyperthermia emergency cart:...Dantrolene (36 amps)."</p> <p>Review of the facility's "Malignant Hyperthermia Cart" policy revised May 2008 revealed the following documentation: "1. The malignant hyperthermia cart will be checked by the R.N. [Registered Nurse] in surgery once a month to make sure all necessary medications and supplies...are present and in date...Medicine drawer checked daily Monday through Friday on regular workdays and on weekends and holidays of OR is called in...3. A copy of malignant hyperthermia protocol reviewed annually is located on top pf the cart. Instructions on dosage and administration of the individual medications are kept in the drawers with the meds they pertain to...The malignant hyperthermia care is located in the O.R. holding area and kept locked at all times."</p> <p>Observation on 6-25-08 in the main Operating Room at 10:50 AM revealed the Malignant Hyperthermia Cart contained only 30 vials of Dantrolene (a medication used to treat Malignant Hyperthermia/a biochemical chain reaction response "triggered " by commonly used general anesthetics. General signs of the MH crisis include a rise in heart rate, increased body metabolism, muscle rigidity and/or fever that may</p>	A 492		

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NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 492	<p>Continued From page 9</p> <p>exceed 110 degrees F. Complication include: cardiovascular collapse, brain damage, internal bleeding or failure of other body systems. This is a potentially fatal syndrome.). During an interview at 10:55 AM the Director of Surgical Services revealed that the 30 vials were all that were ever on the cart. Further observation revealed no instructions were available on how to use the Dantrolene.</p> <p>During an interview on 6-25-08 at 2:50 PM the Director of Pharmacy Services alleged 6 vials of Dantrolene were in the Recovery Room (PACU). Observation at 3:00 PM in the PACU revealed there were no vials of Dantrolene present. This finding was confirmed by the Vice President of Clinical Services.</p> <p>On 6/25/08 at 3:15 PM, interview with 2 nurses in the Cardiac Care Unit revealed no Dantrolene was kept in that department. This was also confirmed by the Vice President of Clinical Services during observation and interview.</p> <p>On 6/25/08 at 3:25 PM the Director of Pharmacy Services stated to the surveyor and the Vice President of Clinical Services that the other 6 vials were in the Labor and Delivery Department (L&D). The Director further stated "it used to be in the PACU but I forgot it is now in the L&D." Observation in the L&D at 3:40 PM revealed there were 6 vials of Dantrolene in the L&D Pixes (medication cart). No instructions for the use of the Dantrolene were found at the time of observation. Interview with the Director of the Women's Center on 6-26-08 at 10:00 AM confirmed that there were no instructions on use of the medication in the cart, and the Director further stated when asked where the instructions</p>	A 492			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008 4:05pm
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 492	Continued From page 10 were "I guess we would look in the policy manual."	A 492			
A 505	482.25(b)(3) UNUSABLE DRUGS NOT USED Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. This STANDARD is not met as evidenced by: Based on observation, interview, and policy review, it was determined the facility failed to remove one expired drug from usable stock. The findings included: Observation during a tour of the facility off-site rehabilitation clinic at the "Maple Street Location" revealed one 5 milliliter (ml) vial (Lot #201791) of Dexamethasone Sodium Phosphate 4 milligrams (mg) per ml with an expiration date of April 2008. The findings were confirmed in an interview with the scheduler (only staff member on-site at time of tour) on 6/24/08 at 1:10 PM. Review of the facility policy entitled, "Out-Dated Drugs (Storage and Disposition)" dated February 2006 revealed the following: "The Pharmacy stock and all drug storage areas are checked monthly for out-dated drugs." "Some drugs are destroyed in the hospital by either being poured down the sink or shipped out according to the hospital's waste disposal procedure."	A 505			
A 619	482.28(a) ORGANIZATION Organization	A 619			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 619	<p>Continued From page 12</p> <p>j. A Southbend 6 burner stove was observed with large amounts of grease/debris stuck to all parts of the stove.</p> <p>k. Oven #1 and #2 had large amounts of grease/debris noted on the knobs, inside and front of ovens.</p> <p>The grease trap located in front of the stove and ovens was noted to be full with large pieces of food in the trap also.</p> <p>Observation of the dry food storage area revealed the following:</p> <p>l. A 9.7 ounce bag of Splenda with brown, sticky debris on the outside of the package.</p> <p>m. A plastic canister of Honey Cajun mix with a lid that was not covering the container.</p> <p>3. The tops of raisin/chocolate covered nuts container, and container of walnuts with sticky matter on the tops with debris stuck to them.</p> <p>o. A 1 gallon plastic bottle of browning seasoning sauce without a lid with plastic wrap covering it. The plastic wrap with a hole in opening.</p> <p>p. A 1 gallon container of hickory seasoning/soy sauce with brown liquid on the outside of the container.</p> <p>q. Multiple cans of beets (6 pounds), black bean (6 pounds, 4 ounces), sliced green olives (3 pounds 7 ounces), instant chocolate/strawberry mouse cans with a thick coat of dust on the lids.</p> <p>r. Large plastic bins of hard boiled, peeled eggs, and cranberry nut batter with pieces of brown matter on the lids.</p> <p>s. A 20 pound box of frozen beans in the walk in freezer not covered.</p> <p>All observations were confirmed by the Administrator and the Director of Nutritional Services.</p> <p>2. During a tour of the dietary department on</p>	A 619			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/23/2014
FORM APPROVED

OMB NO. 0938-0891
September 26, 2014

4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 619	Continued From page 13 06/25/08 it was observed the floor in the dish-washing area was 3/4 covered with standing water which caused a safety hazard for employees. This finding was confirmed with the Director of Nutrition Services on 06/25/08.	A 619			
A 724	482.41(c)(2) FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This STANDARD is not met as evidenced by: Based on observation and interview it was determined the facility failed to maintain the premises, supplies and equipment in a clean and sanitary manner which promotes safety and quality for staff and patients. The findings include: During a tour of the dietary department on 06/25/08 it was observed the floor in the dish-washing area was 3/4 covered with standing water which caused a safety hazard for employees. This finding was confirmed with the Director of Nutrition Services on 06/25/08.	A 724			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/23/2014
FORM APPROVED

OMB NO. 0938-0291
September 26, 2014
4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 440003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
A 724	<p>Continued From page 14</p> <p>During a tour of the PACU [Post Anesthesia Recovery Room] on 06/25/08 it was observed the monitor tops, handwashing gel containers, and stands were covered with a thick layer of dust in five bays in the department.</p> <p>This finding was confirmed with the Director of Surgical Services on 06/25/08.</p> <p>During a tour of the Surgical Services Department on 06/25/08 it was observed the floor in Endoscopy Room #2 was sticky.</p> <p>This finding was confirmed with the Director of Surgical Services on 06/25/08.</p> <p>Observation on 6/24/08 at 4:45 PM during a tour of the off-site rehabilitation clinic at the "Sumner Crossroads, White House Location" revealed a Hydrocollator, a device used to heat wet hot packs, in the main treatment area that contained wet hot packs for heat therapy. Continued observation revealed no evidence of temperature logs to check the heat level of the water and heat packs.</p> <p>An interview with the physical therapist confirmed the finding and that the facility policy is to check the water temperature daily and document on a log.</p> <p>Observation on 6/24/08 at 4:55 PM revealed a freezer used to store ice packs for ice/cold therapy. Further review revealed no temperature logs to check the temperature of the device to ensure proper operation and temperature level.</p> <p>An interview with the physical therapist at the time of the observation confirmed the finding and that the facility policy is to check the freezer temperature daily and log the temperature.</p>	A 724			

Post-Certification Revisit Report

September 25, 2014

4:05pm

Public reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork Reduction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number 440003	(Y2) Multiple Construction A. Building B. Wing	(Y3) Date of Revisit 8/6/2008
Name of Facility SUMNER REGIONAL MEDICAL CENTER		Street Address, City, State, Zip Code 555 HARTSVILLE PIKE GALLATIN, TN 37066

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix <u>A0385</u> Reg. # <u>482.23</u> LSC _____	Correction Completed 07/31/2008	ID Prefix <u>A0405</u> Reg. # <u>482.23(c)(1)</u> LSC _____	Correction Completed 07/31/2008	ID Prefix <u>A0457</u> Reg. # <u>482.24(c)(1)(III)</u> LSC _____	Correction Completed 07/31/2008
ID Prefix <u>A0466</u> Reg. # <u>482.24(c)(2)(v)</u> LSC _____	Correction Completed 07/31/2008	ID Prefix <u>A0490</u> Reg. # <u>482.25</u> LSC _____	Correction Completed 07/31/2008	ID Prefix <u>A0492</u> Reg. # <u>482.25(a)(1)</u> LSC _____	Correction Completed 07/31/2008
ID Prefix <u>A0505</u> Reg. # <u>482.25(b)(3)</u> LSC _____	Correction Completed 07/31/2008	ID Prefix <u>A0619</u> Reg. # <u>482.28(a)</u> LSC _____	Correction Completed 07/31/2008	ID Prefix <u>A0724</u> Reg. # <u>482.41(c)(2)</u> LSC _____	Correction Completed 07/31/2008
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed

Reviewed By _____ State Agency	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____
Reviewed By _____ CMS RO	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____
Followup to Survey Completed on: 6/26/2008		Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO		

PRINTED: 09/23/2014
FORM APPROVEDSeptember 25, 2014
4:05pm

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 404	<p>1200-8-1-.04 (4) Administration</p> <p>(4) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A hospital which violates a required policy also violates the rule and regulation establishing the requirement.</p> <p>This Rule is not met as evidenced by: Based on review of facility documents, observation, and interview it was determined the facility failed to follow its written policies for temperature monitoring and medications.</p> <p>The findings include:</p> <p>During a tour of the Labor and Delivery Department on 06/24/08 it was determined the temperature in the refrigerator which is designated for breast milk was 28 degrees F [Fahrenheit]. Review of the facility policy for this refrigerator revealed the temperature was to be in the range of 35 degrees to 40 degrees F. Review of the temperature log for this refrigerator revealed the temperature was consistently in the 20 - 30 degree range for the months of May and June, 2008. There was no documentation that any corrective action had been instituted.</p> <p>Interview with the Director of Women's Services on 06/24/08 at 2:30 PM in the Administrative Conference Room revealed a work order had not been initiated to correct the temperature. The Director continued on that the staff had been turning up the temperature to the correct range. This was not documented on the temperature log.</p>	H 404			

Division of Health Care Facilities

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

07/14/08

PRINTED: 09/23/2014

FORM APPROVED

Division of Health Care Facilities

September 25, 2014

4:05pm

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNP531116	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 06/26/2008
NAME OF PROVIDER OR SUPPLIER SUMNER REGIONAL MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 555 HARTSVILLE PIKE GALLATIN, TN 37066			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
H 404	<p>Continued From page 1</p> <p>During a tour of the Surgical Services Department on 06/25/08 it was determined the temperature of the blanket warmer in the Operating Room was 151 degrees F and the temperature of the blanket warmer in the PACU[Post Anesthesia Recovery Room] was 134 degrees F. Review of the facility policy revealed the temperature of the blanket warmers is to be 120 degrees F.</p> <p>This finding was confirmed with the Director of Surgical Services on 06/25/08.</p>	H 404			

September 25, 2014

4:05pm

State Form: Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number TNP531116	(Y2) Multiple Construction A. Building B. Wing	(Y3) Date of Revisit 8/6/2008
Name of Facility SUMNER REGIONAL MEDICAL CENTER	Street Address, City, State, Zip Code 555 HARTSVILLE PIKE GALLATIN, TN 37066	

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the Identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix <u>H0404</u> Reg. # <u>1200-8-1-.04 (4)</u> LSC _____	Correction Completed 07/31/2008	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed
ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed	ID Prefix _____ Reg. # _____ LSC _____	Correction Completed

Reviewed By _____ State Agency	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____
Reviewed By _____ CMS RO	Reviewed By _____	Date: _____	Signature of Surveyor: _____	Date: _____

Followup to Survey Completed on: 6/26/2008	Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO
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**September 25, 2014
4:05pm**

Attachment 11

SUPPLEMENTAL #2

September 29, 2014
11:40am

September 29, 2014

HAND DELIVERY

Jeff Grimm, Examiner
Tennessee Health Services and
Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Certificate of Need Application CN1409-041
Summer Regional Medical Center –
Initiation of PET Service on Outpatient Campus of Hospital

Dear Mr. Grimm:

Responses to the questions in your letter dated September 29, 2014, are below. The required affidavit is enclosed at the end of this response. Please let us know if you need additional information.

1. Section B, Project Description, Item II.E. and Section C, Economic Feasibility, Item 1 (Project Cost Chart)

The revised quote extending the expiration date to 12/22/2014 and the revised Project Cost Chart for the addition of \$199,500 to the cost of the PET/CT unit for sales tax and freight are noted.

However, it appears that the Filing Fee in line E of the chart, should also have been revised as a result of the increase in the cost of the PET/CT unit. It appears that the new fee would amount to \$6,483, an increase of \$449. This change would also change the grand total in line F. Please remit the additional amount and provide a replacement page with the revised Project Cost Chart.

Response: A replacement page (20-R(2)) for the Project Cost Chart and a check in the amount of \$449 are enclosed.

*The Pinnacle at Symphony Place
150 3rd Avenue South, Suite 1600
Nashville, TN 37201*

DAN H. ELROD
615.651.6702
dan.elrod@butlersnow.com

T 615.651.6700
F 615.651.6701
www.butlersnow.com

Jeff Grimm
September 29, 2014
Page 2

September 29, 2014
11:40am

Given the 160 miles distance from the cyclotron to the proposed PET/CT location at Sumner Station, what is the life of the material that is required to account for driving times under normal conditions?

Response: SRMC understands that FDG has a half-life of slightly less than 2 hours. Cardinal Health ships FDG daily to its nuclear pharmacy distribution site in Nashville, for subsequent distribution to PET sites in the region that it services. In addition to the cyclotron in Louisville, Cardinal Health has cyclotrons in Knoxville, Birmingham and Memphis that can be the source of FDG. Based on the fact that Cardinal is already servicing PET units in the region, SRMC is confident of Cardinal Health's ability to provide timely delivery of FDG with the requisite degree of radioactivity for PET patients at Sumner Station.

2. Section C, Need. Item 6

The clarification of the methodology used to determine the utilization of the proposed PET service by Sumner & Macon County residents is noted.

Is it correct that, given the higher projected capture rate in Year 3, that utilization, revenue, expenses and net operating income can remain as projected for Years 1 and 2 as identified in the Projected Data Chart? Please confirm.

Response: Yes, the utilization, revenue, expenses and net operating income in Years 1 and 2 are based in SRMC's conservative projections for those years.

3. Section C, Economic Feasibility, Item 4. (Historical Data and Projected Data Chart)

Historical Data Chart - Thank you for the clarification and submission of the Revised Historical Data Chart.

In looking at same, it was noted that inpatient gross operating revenue increased by approximately 25% from \$178,940,000 in fiscal year 2012 to \$222,998,000 in FY2013. What accounts for this change when adjusted admissions only increased by approximately 4% during the period?

Response: The unit of measure used, Adjusted Admissions, factors in outpatient volume as well as inpatient volume. Inpatient volumes increased from 2012 to 2013 disproportionately to increases in outpatient volumes. The same trend has held true in 2014. Since inpatient admissions generate more gross revenue than outpatient admissions, the disproportionately larger increase in inpatient admissions caused inpatient gross revenue to grow by a larger percentage than percentage growth in adjusted admissions.

Projected Data Chart – What is the equivalent amount in procedures that ties to the projected charity cost of \$65,000 in Year 1 of the project (line C.3 of the chart)?

Jeff Grimm
September 29, 2014
Page 3

September 29, 2014
11:40am

Response: The charity care cost of \$65,000 equates to 9 PET scans.

The \$115 per dose cost associated with the FDG/radioactive material and the 160 mile distance from the vendor's cyclotron in Louisville, Ky. is noted. What are the annual amounts for same that are included in the supply costs of the Projected Data Chart (line D.3)?

Response: The FDG cost in Year 1 is projected to be \$27,715 and in Year 2 it is projected to be \$38,755.

Very truly yours,

BUTLER SNOW LLP



Dan H. Elrod

clw
Attachments

September 29, 2014
11:40amAFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DavidsonNAME OF FACILITY: Sumner Regional Medical Center

I, Dan Elrod, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

[Signature]
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 29th day of Sept., 20 14,
witness my hand at office in the County of Davidson, State of Tennessee.

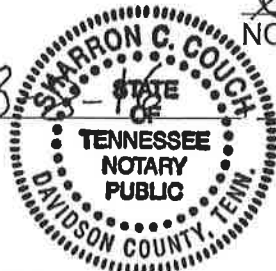
Sharon C. Couch
NOTARY PUBLIC

My commission expires 3-28-16

HF-0043

Revised 7/02

My Commission Expires MAR. 8, 2016



**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954**

DATE: November 28, 2014

APPLICANT: Sumner Regional Medical Center
225 Big Station Camp Boulevard
Gallatin, Tennessee 37066

CON #: CN1409-041

CONTACT PERSON: Dan H. Elrod, Esquire
150 3rd Avenue South, Suite 1600
Nashville, Tennessee 37201

COST: \$2,887,396

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The Sumner Regional Medical Center, LLC, located in Gallatin (Sumner County), Tennessee, seeks Certificated of Need (CON) approval to initiate positron emission tomography (PET) services at its existing outpatient campus known as Sumner Station, located at 225 Big Station Camp Boulevard in Gallatin. The project will require the build-out of approximately 1,425 square feet of existing space and the purchase of G.E. Discovery PET/CT imaging system. The total project cost is approximately \$2,887,896. The total renovation cost is estimated to be \$460,000 or \$322.80 per square foot.

Sumner Regional Medical Center is a 155 bed acute care hospital and is 100% owned by LifePoint Hospitals. LifePoint Hospitals, Inc. is headquartered in Brentwood, Tennessee. LifePoint operates 63 hospitals in 20 States, including 10 in Tennessee.

The total estimated project cost is \$2,687,396 and will be funded through cash reserves as documented by the Chief Financial Officer in Attachment C, Economic Feasibility 2.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The applicant's service area is Macon and Sumner counties.

County	2014 Population	2018 Population	% of Increase/ (Decrease)
Macon	23,188	24,121	4.0%
Sumner	172,262	183,406	6.5%
Total	195,450	207,527	6.2%

Tennessee Department of Health, Division of Policy, Planning, and Assessment-Office of Health Statistics, 2020,
June 2013, Revision

The outpatient campus at Sumner Station is located in an existing building located off Vietnam

Veterans Parkway with easy access, improved parking, and a canopied entrance.

There are currently no PET services available in Sumner and Macon counties. The nearest services are located thirty miles away from Gallatin. The following illustrates the nearest PET services and their utilization.

Davidson	ODC	Imaging Alliance - Nashville PET, LLC	2013	1	Fixed	1722	\$6,025,720.00
Davidson	ODC	Premier Radiology Midtown	2013	1	Fixed	157	\$1,334,293.00
Davidson	PO	Tennessee Oncology, PET Services	2013	1	Fixed	1770	\$5,928,195.00
Davidson	HOSP	TriStar Centennial Medical Center	2013	1	Fixed	273	\$4,075,450.00
Davidson	HOSP	Vanderbilt University Hospital	2013	1	Fixed	3340	\$16,146,409.00

HSDA Equipment Registry

According to the applicant, the project need is based on the lack of PET services for residents in Sumner and Macon counties. The need for PET services is further indicated by the fact cancer rates in Sumner and Macon counties are higher than the statewide average. According to the report Cancer in Tennessee 2005-2009 published by the Tennessee Department of Health, Division of Policy, Planning, and Assessment:

- From 2005-2009, Tennessee had the 16th highest cancer incidence rate in the country and the 6th highest cancer mortality rate;
- Tennessee's cancer incidence rate for the period was 476.8 per 100,000;
- Sumner County's cancer incidence rate for the period was 487.6 per 100,000 2.3% higher than the Tennessee rate; and
- Macon County's cancer incidence rate for the period was 554 per 100,000, 16% higher than the Tennessee cancer incidence rate.

The applicant believes that, given the cancer incidence rate is higher than the statewide incidence in Sumner and Macon counties, it is important that state-of-the-art cancer diagnostic resources be located closer than 30 miles away for the convenience of the service area residents. SRMC is committed to continued moderation (?) and enhancement of its cancer diagnosis and treatment services. In addition to this PET CON, Mammography and CT imaging are already provided at Sumner Station.

SRMC's cancer service has been accredited by the American College of Surgeons. Current services provided include community education, pastoral care, and nutrition services. Patient support groups are available through a partnership with Gilda's Club.

Chemotherapy in the community is provided by Tennessee Oncology, the largest oncology group in the region, which participates in clinical trials through the Sarah Cannon Center. Tennessee Oncology is the only oncology group with a presence in Gallatin. The applicant provides a letter from Tennessee Oncology confirming the applicant's assumption that Sumner Station would ultimately serve at least 50% of the patients from the region that needs PET.

The number and types of physicians at SRMC involved in cancer care includes:

- Radiation oncologist-1 active staff and 16 coverage staff;
- Medical oncologist -2 active staff and 16 consulting/coverage staff;
- General surgeons-4 active staff;

- Urologists-4 active staff;
- Radiologists-9 active staff; and
- Pathologists-4 active staff.

In 2013, 683 Sumner County residents utilized PET providers in Davidson County. The applicant projects 241 and 337 scans in years one and two of the project.

TENNCARE/MEDICARE ACCESS:

The applicant will participate in the TennCare and Medicare programs. The applicant is contracted with all TennCare plans that operate in Middle Tennessee. SMRC's projected gross revenues for radiation therapy from TennCare/Medicaid in year 1 are \$120,000 (6.63%) and gross Medicare revenues are projected to be \$817,500 (45.13%).

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine they are mathematically accurate and the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located in Supplemental 1 of the application. The total project cost is \$2,887,396.

Historical Data Chart: The Historical Data Chart is located in Supplemental 1 of the application. The applicant reported 14,330, 15,146, and 15,967 admissions in 2011, 2012, and 2013, respectively. The applicant reported net operating revenues of \$4,941,000, \$4,304,000, and \$6,406,000 each year, respectively.

Projected Data Chart: The Projected Data Chart is located on page 24 of the application.. The applicant projects 241 and 337 in years one and two, respectively. The total net operating revenue in year one is projected to be \$18,000 and \$65,000 in year two of the project.

The applicant projects an average gross charge of \$7,500. The median charge per the HSDA equipment registry is \$4,834.25. The applicant's proposed charge is slightly over the 3rd Quartile for the State, which is \$7,307.21.

The applicant found no other suitable alternatives to the proposed project.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

The applicant provides a listing of managed care contracts and health providers or organizations in Attachment C, Contribution to Orderly Development of Healthcare-1.

The project should have only positive effects on the healthcare system due to improved patient convenience. The inclusion of PET services in the community will insure Sumner and Macon County residents they can receive quality treatment in their own community without having to travel to Nashville. SRMC would be the only provider in the service area should the CON be approved.

This project will require only 1.0 FTE nuclear medicine technologist to the medical staff.

SRMC has an agreement with Austin Peay University, under which SMRC is a clinical training site for radiation therapy technologists.

SRMC is accredited by the Joint Commission and licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities. The cancer program is accredited by the American

College of Surgeons Commission of Cancer Care. The most recent licensure survey and the plan of correction are included in Attachment C, Orderly Development of Healthcare-7(c).

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

PET Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter.

Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1,600 procedures per year if the unit is operated more than five (5) days per week.

The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

This application is for a fixed PET.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population.

Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

This criterion is not applicable.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

The project appears to be reasonable due to the site being located in an existing building on an outpatient campus. A part-time mobile PET was considered but rejected because a part-time unit would compromise availability and convenience.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

Not applicable.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the

total capacity of 2,000 procedures during the most recent twelve month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures /day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

The applicant projects 241 and 337 scans in years one and two of the project. Due to this being the first PET unit (if approved) in the service area, SRMC believes this criterion is not applicable.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.

- a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

SRMC provides the FDA approval documentation is Attachment B. II. E. 1.

- b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

The applicant agrees to comply with all applicable standards.

- c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

The PET center will be licensed and owned by SRMC, thus operated under the same emergency management plan and procedures that apply to SRMC. Medical emergencies will be transported by ambulance to SRMC.

- d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

The physicians who refer patients will have no financial interest in SRMC or the PET. Procedures will be performed only on patients for whom PET is determined to be medically necessary. SRMC has developed draft protocols and have attached them under Attachment C, Need-PET Standards, Item 6.d.

- e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation

services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

The PET service will be under the medical direction of Dr. Glen Nabors, a board certified radiologist. Other radiologists in Sumner Radiology are also qualified to interpret PET scans.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

The proposed PET will be operated by SRMC as part of the hospital, and Dr. Nabors is an active member of SRMC's staff.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant agrees.

8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;
- c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or
- d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant believes they should receive special consideration under this criterion for the following reasons:

According to the applicant, the project need is based on the lack of PET services for residents in Sumner and Macon counties. The need for PET services is further indicated by fact cancer rates in Sumner and Macon counties are higher than the statewide average. According to the report Cancer in Tennessee 2005-2009 published by the Tennessee Department of Health, Division of Policy, Planning, and Assessment:

- *From 2005-2009, Tennessee had the 16th highest cancer incidence rate in the country and the 6th highest cancer mortality rate;*
- *Tennessee's cancer incidence rate for the period was 476.8 per 100,000;*
- *Sumner County's cancer incidence rate for the period was 487.6 per 100,000 2.3% higher*

- than the Tennessee rate;*
- *Macon County's cancer incidence rate for the period was 554 per 100,000, 16% higher than the Tennessee cancer incidence rate;*
 - *SRMC has a long history as a provider in the TennCare program and contracts with all MCOs in the region;*
 - *All of Macon County and part of Sumner County are designated as Medically Underserved (MUA); and*
 - *No PET service exists in the area and the project is financially feasible.*